

75 microgram film coated tablets **Desogestrel** Daily contraceptive without prescription

PHARMACY GUIDE



Product Information available on page 71

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ORAL CONTRACEPTIVE HANA 75 MICROGRAM FILM COATED TABLETS CAN BE SUPPLIED IN PHARMACY WITHOUT PRESCRIPTION

This Pharmacy guide is designed to help you build and test your own knowledge of Hana.

An online version of this guide, containing identical information, is also available. If you would prefer to use the online version, you can access it here: https://info.hanapharmacist.co.uk/training.

The content of the guide is fully aligned with legal documentation, that is, the SmPC, unless stated otherwise.

THE PHARMACIST'S ROLE IN SUPPLYING HANA

Pharmacists have a key role to play in supplying Hana without prescription. It is the pharmacist's role to help women assess whether Hana is a suitable option for them. They will check that there are no contraindications to supply, and know when to refer women to their doctor for advice if they have any condition for which there is a warning regarding use of Hana.

This guide has been designed to support pharmacists and their teams to appropriately supply and advise on the use of Hana.

It will help you to make confident recommendations and give appropriate information and advice to women seeking regular oral contraception in your pharmacy.

There will be situations in which you will need to use your professional judgement; apply the principles of risk management in identifying red flags and safety netting, which this guide will help you with.

For full information about Hana, including all contraindications, warnings and possible side effects, please refer to the Summary of Product Characteristics (SmPC; https://info.hanapharmacist.co.uk/smpc) and the Patient Information Leaflet (PIL; https://info.hanapharmacist.co.uk/pil).



GUIDE AND ASSESSMENT

There are three parts to this training to support your conversations with women seeking Hana.



Includes an overview of the reproductive cycle and explains how Hana works. It provides information about the safety and efficacy of Hana, and who Hana is and is not indicated for.



Outlines what you need to do, the questions you need to ask and the advice you need to give women who request Hana in your pharmacy. This includes managing repeat supply and continued use.



Demonstrates how consultations for different supply situations could work in practice, supported by corresponding animated videos available online.

You will be assessed on all 3 parts for Continuing Professional Development (CPD) certification.

The guide and all useful documents can be downloaded and printed using the URLs throughout.

LEARNING OUTCOMES AT A GLANCE

Part

1	Understand the basic elements
2	Know the key facts about Hana
3	Understand how effective Hana for maximum effectiveness
4	Know the contraindications and when to refer to doctor

of the menstrual cycle a and understand how it works a is and how it needs to be taken

d warnings for Hana and know



Hana is a progestogen-only oral contraceptive pill (POP), which contains the progestogen desogestrel.¹

As a pharmacy medicine, without prescription, it is for women of childbearing age who want to prevent pregnancy.¹

Hana is taken daily, at the same time each day, without any breaks between packs.¹

Key facts about Hana



Like other POPs, Hana is suitable for most women, including during breastfeeding and for women who are unable to or prefer not to use oestrogens¹



If taken as recommended, i.e. at the same time every day without a break between packs, Hana inhibits ovulation in up to 97% of cycles^{2,3}



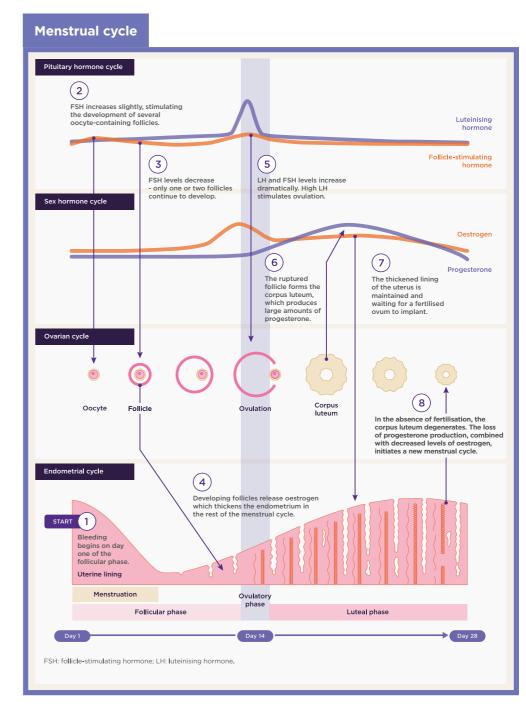
Hana has a 12-hour window for missed pills if necessary¹



Oral contraceptive pills do not protect against sexually transmitted infections, only condoms will do so⁴



- The normal menstrual cycle varies in length⁵
- For a woman with a 28-day cycle, the egg grows through the first 12 days or so, reaching maturity at the time of ovulation (which may vary between individual women and between individual cycles)5



Adapted from Aitken RJ, et al. 2008.5

In order to understand how Hana works it is useful to review the menstrual cycle.

• In the absence of conception, menses occur around 14 days after ovulation when the endometrium is shed⁵



Watch or download an animation detailing the mechanism of action of Hana here: https://info.hanapharmacist.co.uk/moa.



Hana is a POP that contains desogestrel, a synthetic progestin that acts by binding selectively to the progesterone receptor.^{1,6} Desogestrel achieves its contraceptive effects primarily by both inhibiting ovulation and by altering the cervical mucus, preventing sperm penetration.¹



During the natural cycle, the secretion of gonadotropin-releasing hormone (also known as GnRH) from the hypothalamus leads to increased levels of follicle-stimulating hormone (also known as FSH) and luteinising hormone (also known as LH).⁷ The surge in these hormones and corresponding rise in oestradiol in turn leads to ovulation.⁷



Desogestrel suppresses the secretion of FSH and LH by producing a negative feedback on the synthesis and release of the GnRH from the hypothalamus.⁷ This leads to the absence of the FSH and LH surge, which is essential to mature the developing dominant follicle, and trigger ovulation.⁷ The suppression of ovulation also leads to the reduction of oestradiol to a level corresponding to the early follicular phase.¹ By this mechanism, desogestrel has been shown to inhibit ovulation in up to 97% of cycles, making this its primary mechanism of action.^{2,3}



Notice that ovulation can re-start at any time if Hana is not taken as directed or if a pill is missed. This is why it is important to take Hana at the same time every day.

In the first half of the natural menstrual cycle, oestrogen causes the cervical mucus to become progressively thinner, alkaline, and clear.⁸ This culminates in the production of copious, watery, 'egg-white' mucus around the time of ovulation, allowing the free passage of sperm from the cervix into the uterine cavity to achieve fertilisation.⁸



Desogestrel prevents sperm reaching the egg by mimicking the secretion of progesterone, which causes the mucus to become thick, white, and opaque, with a sticky consistency. The resulting action of this thick plug is to make it impermeable to sperm penetration.⁸

In summary, Hana prevents conception in two independent ways. Firstly, by preventing ovulation in up to 97% of cycles,^{2,3} and secondly, by thickening the cervical mucus to create a plug that sperm are unable to penetrate.⁸

Importance for tablet-taking

If Hana is taken as recommended, at the same time every day, ovulation will not occur.¹ However, if a pill is missed, the effect of Hana on ovulation may diminish and an egg may start to develop if it is more than 12 hours late.¹ The effect of Hana on the viscosity of the cervical mucus may also be reversed, hence sperm may be able to enter the uterus again. This means that although Hana should be taken at the same time every day, if a woman is up to 12 hours late in taking her pill, she should take it as soon as she remembers within those 12 hours.¹ She should take the next pill at the usual time, without needing to use any additional precautions.¹

The Hana 12-hour window for missed pills

Hana should be taken at the same time every day, i.e. the doses are 24 hours apart.¹

The effect of Hana on ovulation may diminish from 12 hours after the next dose should have been taken.¹

This means that there are an additional 12 hours in which to take a missed pill before the effect of Hana on ovulation may diminish and an egg may start to develop.

-



Two clinical studies have clearly shown that Hana is effective in inhibiting ovulation and in preventing pregnancy.¹

STUDY 1 STUDY 2 In the first study, ovulation occurred In the second study, which compared in only 1% (1/103) of menstrual cycles Hana to another POP, the Pearl Index and inhibition of ovulation started from was 0.4 for Hana.¹⁰ the first cycle after women started taking Hana.^{1,9}

The Pearl Index (named after the American scientist Raymond Pearl) is a measure of the effectiveness of contraceptives: the smaller the Pearl Index, the more effective the method of contraception. E.g. a Pearl Index of 0.1 means that 1 in 1000 women who use the same contraceptive for 1 year becomes pregnant.

A Pearl Index of 0.4 equates to 4 women in a thousand getting pregnant on Hana in one year.

- This is similar to the pregnancy rates for combined oral contraceptives in clinical studies¹
- It is estimated that, if used as recommended:
 - 4 women in 1000 would get pregnant in one year using a sympto-thermal method (ovulation method with calendar in the pre-ovulatory phase and basal body temperature in the postovulatory phase)¹¹
 - O 20 women in 1000 would get pregnant in one year using condoms¹¹
 - 30 women in 1000 would get pregnant in one year using an ovulation method (cervical mucus) to identify times when there is a risk that they could get pregnantⁿ
 - 180 women in 1000 would get pregnant in one year using spermicides alone¹¹

WHO CAN USE HANA

Hana is indicated as an oral contraceptive in women of childbearing age.¹

Contraindications to Hana

There are a few situations in which Hana should not be used.¹

Women who:1

- have breast cancer or other known or • have unexplained vaginal bleeding between their periods or repeatedly have bleeding suspected sex-steroid sensitive cancers, such as ovarian or uterine cancer after sex. Women experiencing this type of bleeding should be referred to their doctor for have, or have had, severe liver disorders that further investigation
- have not resolved (blood tests show the liver function values have not returned to normal)
- have active venous thrombosis or pulmonary embolism*

* A history of these conditions is not a contraindication for use of Hana; these conditions are not thought to be caused by POPs.¹

Excipients in Hana

Ingredients:1 Alpha-tocopherol, Lactose monohydrate, Maize starch, Povidone K25, Stearic acid

Film coating:1 Hypromellose, Macrogol 400, Titanium dioxide (E 171)



- are allergic to desogestrel or to any of the other ingredients in Hana; refer to the box below for a list of ingredients
- are pregnant

When to refer to a doctor before use of Hana

There are other conditions in which Hana might be suitable, but a doctor would need to assess the woman first:^{1,4}

- history of breast, ovarian or uterine cancer
- current liver cancer or other liver disorders
- Type 1 or Type 2 diabetes

Counsel women before and during use of Hana

Hana can be used by women with a history of chloasma or thromboembolic disorders, or who have high blood pressure, but they should be counselled as follows before supply:¹

- chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) may occasionally occur, especially in women who have had it before; these women should avoid exposure to the sun or UV radiation
- there is the possibility of a recurrence of venous thrombosis or pulmonary embolism in women with a history of these conditions
- women who develop sustained hypertension during use of Hana, or a significant increase in blood pressure that does not adequately respond to antihypertensive therapy, should see their doctor to decide whether Hana should be discontinued (pharmacists are not expected to check/monitor blood pressure prior to or during supply)



Hana can be used by women who are breastfeeding.¹ Although a small amount of the active substance of Hana passes into the milk. Hana does not appear to influence the production or the quality of breast milk.¹ However, there have been infrequent postmarketing reports of a decrease in breast milk production while using desogestrel.¹ The development and growth of a breastfed infant, whose mother uses Hana, should be carefully observed.¹ However, no effect of desogestrel in breastfed newborns/infants has been shown.¹

Guidance on what to do if you suspect a woman is requesting Hana for off-label use

- contraceptive pill, and may believe that Hana would have similar beneficial effects
- While it would be inappropriate for pharmacists to ask women directly whether they are requesting Hana for any reason other than pregnancy prevention, it is important for pharmacists to be aware of this, and if asked be able to respond that:
 - o there is very little evidence that Hana would be better than placebo in improving dysmenorrhoea or endometriosis
 - o it is unlikely to postpone menses for social (or other) reasons

Please read the SmPC for full details of contraindications, warnings and precautions. Remind every woman to read the PIL carefully before taking Hana.



• Women may be aware of the potential non-contraceptive benefits of the combined oral

o there is no evidence to support its effectiveness for premenstrual syndrome, acne (which may get worse), or heavy menstrual bleeding



The product information for any concomitant medicines needs to be consulted to identify potential interactions and any recommendations.¹

Some medicines or herbal remedies impact CYP enzymes and affect the clearance of contraceptive hormones, and may have an impact on the contraceptive efficacy of Hana.¹ These can be divided into:



Substances may increase the clearance of contraceptive hormones by enzyme induction, which may lead to breakthrough bleeding and/ or contraceptive failure.¹

Women need to use additional precautions during treatment with and for 28 days after stopping these enzymeinducing medicines. If these medicines are used chronically or long term, Hana may not be the most appropriate method of contraception and the woman should be referred to her doctor for further advice.^{1,4}

These medicines include treatments for:^{1,4}

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate, phenobarbital)
- tuberculosis (e.g. rifampicin, rifabutin)
- HIV infections (e.g. efavirenz)
- pulmonary arterial hypertension (e.g. bosentan)
- depression (the herbal) remedy St. John's Wort)
- fungal infections (e.g. griseofulvin)



Substances may have variable effects on the clearance of contraceptive hormones, increasing or decreasing the plasma concentrations of progestins, which may have a clinically relevant net effect in some cases.1

In case of doubt, women should use additional precautions during treatment with these medicines. If these medicines are used chronically or long term, Hana may not be the most appropriate method of contraception and the woman should be referred to her doctor for further advice.^{1,4}

These medicines include treatments for:1,4

- HIV infections (e.g. ritonavir, nelfinavir, nevirapine)
- hepatitis C virus infection (e.g. boceprevir, telaprevir)



If these medicines are used chronically or long term, the woman should be referred to her doctor for further advice.^{1,4}

These medicines include treatments for:^{1,4}

- fungal infections (e.g. itraconazole, fluconazole)
- bacterial infections (e.g. clarithromycin, erythromycin)
- high blood pressure, abnormal heart rhythm or angina (e.g. diltiazem)

Use of Hana with emergency contraception

Women starting or resuming Hana:1

If a woman wishes to start Hana after using emergency contraception, it is advisable to start tablettaking on day 1 of the woman's natural cycle.

If it is considered necessary to start sooner (referred to as quick starting), or if Hana is being resumed after inconsistent use, the following advice should be noted:

- levonorgestrel she can start or restart Hana that same day and should use additional contraceptive measures (abstinence or barrier methods) for the first 7 days of Hana use
- ulipristal acetate* she should wait 5 days (120 hours) after taking ulipristal acetate before starting or restarting Hana. She should also use additional contraceptive measures an additional 7 days after starting or restarting Hana (i.e. 12 days in total)

Additional information on quick starting is provided on page 30. However, it should be noted that guick starting is outside the approved use of Hana and its SmPC.

* Emergency contraception containing ulipristal acetate and Hana both bind to the progesterone receptor.¹ Concomitant use may result in reduced efficacy of both Hana and ulipristal and is therefore not recommended.¹

Please read the SmPC for full details of contraindications, warnings and precautions. Remind every woman to read the PIL carefully before taking Hana.

(abstinence or barrier methods) during the 5 days of waiting to start or restart Hana and for



OK, now it's time to test your knowledge. Answer a few short questions on Part 1 below.

Q1 How does Hana work? Select all that apply

- Increasing viscosity of the cervical mucus
- Preventing the fertilised egg from implanting in the womb
- Delaying ovulation
- Inhibiting ovulation

Q2 How should Hana be taken to maximise effectiveness? Select all that apply

- For 21 days with a 7-day break at the end of the pack
- At the same time each day
- Continuously. Every day without a break between packs
- Every day, can be at a different time each day

Q3 In which of these situations should Han Select either CAN be used or should NO

- Pregnancy
- Breastfeeding
- Aged <18 years
- A current blood clot in the legs (veno lungs (pulmonary embolism)
- Severe liver disorders where the liver not returned to normal
- Current sex-steroid sensitive malignar types of breast cancer
- Allergy to desogestrel
- Lactose intolerance
- No previous pregnancy
- Unable to take oestrogens
- A blood clot in the legs (venous thron (pulmonary embolism) in the past

Q4 Which of the following medicines or he effectiveness of Hana?

Select all that apply

- Phenytoin
- Paracetamol
- Rifampicin
- Bosentan
- St. John's Wort
- Efavirenz
- Ibuprofen
- Carbamazepine
- Ulipristal acetate

Turn to page 61 to check your answers.

erbal remedies can reduce the		CAN be used	Should NOT
function values have			
function values have			
function values have			
ncies such as certain	us thrombosis) or		
nbosis) or lungs	function values have		
	ncies such as certain		
erbal remedies can reduce the	nbosis) or lungs		
erbal remedies can reduce the			
	erbal remedies can re	duce the	



LEARNING OUTCOMES AT A GLANCE

Identify whether a woman seeking regular oral contraception is suitable or unsuitable for Hana and know what advice to give to women in different situations:

NEW OR HISTORICAL USER OF DESOGESTREL

First-time supply of Hana to women who have not used desogestrel before, or supply of Hana to women who have not used it for several months

CURRENT OR RECENT USER OF DESOGESTREL

Repeat supply of Hana to women who have purchased Hana from a pharmacy

Changing supply of desogestrel from doctor to pharmacy: women who have been prescribed desogestrel and now want to purchase Hana without prescription

Know when to refer the woman to her doctor

Know the key information that should be communicated to women purchasing Hana in each of these different situations

SUPPLY SITUATIONS

Hana is for women of childbearing age who want to prevent pregnancy.¹

Situations in which Hana should not be used were listed in Part 1. Turn back to page 11 to remind yourself when Hana is NOT a suitable form of contraception or when a woman should be referred to her doctor before she can be provided with Hana.

You could have women in your pharmacy requesting Hana who:

have never used desogestrel before or who have not used it for several months - first-time supply; this includes women:

- who have never used any form of contraception, or who have previously used desogestrel but not taken it for several months
- who are currently using or have previously used other regular hormonal contraception
- who are currently using or have previously used other non-hormonal contraception

are currently using or have recently used Hana, purchased from a pharmacy - repeat supply

are currently using or have recently used desogestrel, prescribed by their doctor - changing supply

How you check suitability for Hana and the advice you give will be different depending on the circumstances.

3

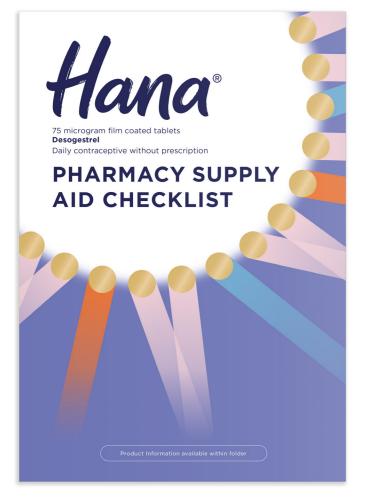
To guide you in your consultations with women requesting Hana in pharmacy, a Pharmacy supply aid checklist has been developed for you to have within easy reach. This consists of:

- a short checklist for women who have never used desogestrel before or who have not used it for several months to complete
- a useful pharmacy supply aid that matches up with the checklist detailing additional questions to ask and responses to give; this supply aid also includes guidance for consultations with women who are currently using or have recently used desogestrel

You will have received a printed copy of the Pharmacy supply aid checklist with this guide. Use of this material is optional, and you are advised to use your professional judgement to decide when and how to use it. You can also download the Pharmacy supply aid checklist here: https://info.hanapharmacist.co.uk/checklist.

A useful algorithm that further clarifies the questions and responses for the different supply situations is available as Appendix 1, is included with the Pharmacy supply aid checklist, and can also be downloaded here: https://info.hanapharmacist.co.uk/algorithm.

The information on the following pages is intended to support your use of the Pharmacy supply aid checklist in pharmacy: it ties together the questions women will be asked on the checklist with pharmacist responses as outlined in the pharmacy supply aid, providing additional rationale and guidance.



Pharmacy supply aid and consumer checklist

Hana	HANNA CHECKLIS This hort checklist will help to determinel Hana is the right oral contraceptive for you, and will help up pharmacist give you good advice. Please scratch of your answer to each of the questions and return this card to your pharmacist or medicines counter assist when finished, who will use the revealed responses guide your discussion.
	Under 16
How old are you?	16-18
	18+
	Yes
Is there any possibility that you may be pregnant?	No
	Unsure
-	Yes
Do you experience any bleeding between your periods or after sex?	No
periods or alter sex?	Unsure
Do you currently have or have you previously had	Yes
any health conditions? (e.g. cancer, liver disorders or jaundice, a blood	No
clot, diabetes, high blood pressure)	Unsure
	Yes
Do you have any allergies?	No
	Unsure
Are you currently taking any regular medication or herbal remedies, or have you recently taken any other medication?	Yes
	No
	Unsure

FIRST-TIME SUPPLY – using the Pharmacy supply aid checklist to check suitability in women who have never used desogestrel before or who have not used it for several months

Before using the checklist to check suitability for a first-time supply of Hana, ask the woman if she is aware of other contraceptive options. If not, signpost her to a reliable source such as the "Contraceptive options" leaflet (available here: https://info.hanapharmacist.co.uk/leaflet) or https://www.nhs.uk for information, and advise her to see her doctor if she is interested in an option other than Hana. Confirm she is willing for you to check her suitability for Hana, and supply it if appropriate, while she evaluates other options.

If, after using the checklist, you establish that the woman is suitable for Hana, you can provide her with a maximum 3-month first-time supply. Encourage the woman to advise her doctor that she has been supplied with Hana in pharmacy.

Checklist question	Guidance on
How old are you?	Given the need t supplied to the e
	There are addition age, so if there is should be asked
	Guidance on wh 16 years of age i
Is there any possibility that you may be pregnant?	Hana is not suita on excluding pre the next section
Do you experience any bleeding between your periods or after sex?	Hana is not suita vaginal bleeding bleeding after s doctor for invest
	Women can exp it is important to unexplained vag

pharmacist action

to check suitability, Hana should only be end user.

ional checks for women less than 16 years of is any uncertainty around her age, a woman d her birth year when she requests Hana.

hat to do if a woman requesting Hana is under is provided in the box on page 23.

able for women who are pregnant:¹ guidance regnancy before starting Hana is provided in n.

able for women who have unexplained ng between their periods or repeatedly have sex; the woman should be advised to see her stigation to exclude any underlying pathology.¹

perience bleeding disturbances on Hana so to understand the cause of any pre-existing ginal bleeding before starting Hana.¹

Checklist question

Do you currently have or have you previously had any health conditions? (e.g. cancer, liver disorders or jaundice, a blood clot, diabetes, high blood pressure)

Guidance on pharmacist action

Hana is not suitable for women who have:1

- breast cancer or other known or suspected sex-steroid sensitive cancers, such as ovarian or uterine cancer
- severe liver disorders that have not resolved (blood tests show the liver function values have not returned to normal)
- active venous thrombosis or pulmonary embolism

Women should see their doctor to assess suitability for Hana before being provided with it if they have:^{1,4}

- history of breast, ovarian or uterine cancer
- current liver cancer or other liver disorders
- Type 1 or Type 2 diabetes

If a woman is referred to her doctor to check any contraindications or warnings to determine suitability for Hana, the woman should be advised that if her suitability is confirmed, she can return to the pharmacy to obtain Hana.

Women with a history of chloasma or thromboembolic disorders, or high blood pressure, should be counselled before or during use of Hana:^{1,4}

- chloasma may occasionally occur, especially in women who have had it before; these women should avoid exposure to the sun or UV radiation
- there is the possibility of a recurrence of venous thrombosis or pulmonary embolism in women with a history; these women should be advised to see a doctor urgently if they experience symptoms of thromboembolic disorders e.g. warm or swollen, painful leg; shortness of breath; or coughing up blood
- women who develop sustained hypertension during use of Hana, or a significant increase in blood pressure that does not adequately respond to antihypertensive therapy, should see their doctor to decide whether Hana should be discontinued (pharmacists are not expected to check/ monitor blood pressure prior to or during supply)

Checklist question	Guidance on p
Do you have any allergies?	Hana is not suitab desogestrel or to example lactose. ¹ ingredients, or rea
Are you currently taking any regular medication or herbal remedies, or have	Some medicines of contraceptive hor contraceptive efficient
you recently taken any other medication?	The prescribing in needs to be consu any recommendat
	If enzyme-inducin intended for short woman but she sh whilst she is taking she stops taking t impacting CYP en term, Hana may n contraception and doctor for further
	Refer back to pag enzymes; read the
	Emergency contra Hana both bind to use may result in r and is therefore no after emergency o is expanded later
Guidance on what to do if a wo	oman requesting Har
You may receive requests for or age. It is important that you have safeguarding children and yulo	ral contraception from ve undertaken approp

You may receive requests for oral contraception from women younger than 16 years of age. It is important that you have undertaken appropriate training (e.g. CPPE module on safeguarding children and vulnerable adults) to be able to supply Hana with confidence and are fully aware of the Fraser Guidelines surrounding consent and confidentiality on sexual health services in women younger than 16 years of age. This guidance allows healthcare professionals to give advice and treatment provided they are satisfied that:¹²

- the young person will understand the advice and understands what is involved
- the young person cannot be persuaded to inform their parents, or allow the healthcare professional to inform their parents
- the young person is very likely to begin, or continue to have, sexual intercourse without contraception

n pharmacist action

table for women who are allergic to to any of the other ingredients in Hana, for se.¹ Turn back to page 11 for a reminder of the read the SmPC.

es or herbal remedies affect the clearance of hormones, and may have an impact on the efficacy of Hana.^{1,4}

g information for any concomitant medicines nsulted to identify potential interactions and dations.¹

icing medicines or herbal remedies are nort-term use, Hana can be supplied to the e should be advised to use extra precautions king these substances and for 28 days after ig them.¹⁴ If medicines or herbal remedies enzymes are used chronically or long y not be the most appropriate method of and the woman should be referred to her her advice.¹⁴

bage 14 for a list of medicines impacting CYP the SmPC for a full list of drug interactions.

ntraception containing ulipristal acetate and d to the progesterone receptor.¹ Concomitant in reduced efficacy of both Hana and ulipristal e not recommended.¹ Guidance on taking Hana cy contraception was introduced in Part 1, and ter in Part 2.

Hana is under 16 years of age

- without contraceptive advice or treatment, the young person's physical or mental health (or both) would suffer
- the young person's best interests require them to receive contraceptive advice or treatment with or without parental consent

FIRST-TIME SUPPLY - excluding pregnancy

Women who have not recently been pregnant	Women who have recently been pregnant	
	Following childbirth	Following miscarriage, abortion or ectopic pregnancy
Pregnancy can reasonably be excluded if the woman: ¹ has not had unprotected sex since the start of her last menstrual period or has been correctly and consistently using a reliable method of contraception (including condoms where those have been used correctly for every episode of sexual intercourse) or has had unprotected sex but only between day 1 and day 5 of her menstrual cycle	Pregnancy can reasonably be excluded if the woman: ¹ • has not had unprotected sex since childbirth or • has had unprotected sex but less than 21 days after childbirth or • is fully breastfeeding, amenorrhoeic and less than 6 months postpartum	Pregnancy can reasonably be excluded if the woman: ¹ • has not had unprotected sex since miscarriage, abortion or ectopic pregnancy or • has had unprotected sex but less than 5 days after miscarriage, abortion or ectopic pregnancy

FIRST-TIME SUPPLY - starting Hana

Directions on when and how to start using Hana in women who are not currently using any contraception, or who are switching from a different form of contraception, are given below.

Advice to give to women who are not currently using any contraception

Ask the woman when she last used contraception. If she has not used contraception recently it may be because she has been pregnant.

The advice you give the woman on starting Hana will be different depending on her situation.

No contraceptive use in the past month	1
	•
Following miscarriage or abortion	
Following childbirth	

The woman should use a reliable form of contraception (current contraceptive or a barrier method) until day 1 of her next menstrual period before starting Hana.¹

- She should be advised that if her period is already late or does not come when she expects it, she may be pregnant and she should do a pregnancy test (at least 3 weeks after the last episode of unprotected sexual intercourse) or see her doctor¹
- Provided the pregnancy test is negative, she can start Hana on day 1 of her next period¹
- If her period comes in the meantime, she can start Hana on day 1 of that period¹

To support you in excluding pregnancy in women requesting a first-time supply of Hana in pharmacy, a Pregnancy exclusion tool has been developed for you to have within easy reach. This consists of useful decision trees, detailing questions to ask and responses to give, for women who have not recently been pregnant, have delivered or have had a miscarriage, abortion or ectopic pregnancy.

Use of this material is optional, and you are advised to use your professional judgement to decide when and how to use it. It is available as Appendix 2, is included with the Pharmacy supply aid checklist, and can also be downloaded here: https://info.hanapharmacist.co.uk/tool.

- Start on day 1, the first day of menstrual bleeding, no need for extra precautions¹
- Can start on days 2-5 of menstrual bleeding, in which case extra precautions are recommended for the first 7 days¹
- Start immediately or within 5 days after miscarriage or abortion, no need for extra precautions¹
- Start any day between day 1 and day 21 after childbirth¹
- Can start later, in which case extra precautions are recommended for the first 7 days¹
- If she has already had unprotected sex, she should take a pregnancy test or see her doctor before starting Hana¹

Advice to give to women who are changing from existing hormonal contraception

Ask the woman what type of hormonal contraception she is currently using and confirm that she has been using it consistently and correctly, with no unscheduled breaks. The advice on when to start Hana depends on the type of hormonal contraception being used.

Switch from combined oral contraceptive pill, vaginal ring or skin patch	 For the combined pill, start the day after the last tablet (if this is an everyday [ED] pill the woman should start the day after the last tablet containing an active substance), no need for extra precautions¹ Start on the day of the removal of the vaginal ring or skin patch, no need for extra precautions¹ Or start the day after the usual tablet-, ring- or patch-free interval or the day after the last non-active tablet (if this is an ED pill), in which case extra precautions are recommended for the first 7 days¹
Switch from progestogen-only method (mini-pill, injection, implant or intrauterine system)	 Switch to Hana from the mini-pill on any day, just take Hana the next day instead of the mini-pill, no need for extra precautions¹ Start on the day the next injection is due, no need for extra precautions¹ Start on the day of the removal of the implant or intrauterine system, no need for extra precautions¹

REPEAT SUPPLY OR CHANGING SUPPLY - using the Pharmacy supply aid checklist to check suitability in women who are currently using or have recently used desogestrel

This includes women who are using desogestrel and have purchased Hana from a pharmacy or have been prescribed desogestrel.

If you establish that the woman is satisfied with and tolerating Hana, you can provide her with a maximum 12-month supply, unless she is under 18 years of age in which case it is a maximum 3-month supply. Encourage the woman to advise her doctor that she has been supplied with Hana in pharmacy if she is changing supply, or if she has not previously advised her doctor in the case of repeat supply.

Pharmacy supply aid reminder	(
Check 1 tablet has been taken at the same time every day, no break between packs and no missed doses	
Check for any problems related to Hana or desogestrel use since initiation	C C C L E
Check for changes in health since last Hana purchase or desogestrel prescription	•

Guidance on pharmacist action

Hana is not suitable for women who are pregnant;¹ guidance on excluding pregnancy in women who are currently using desogestrel is provided in the next section.

• If a woman is not pregnant, she should be supplied with Hana and reminded to start the next pack without any breaks¹

Checking for any side effects and for an opportunity to provide advice on managing common side effects, or referring her to see her doctor.

Lists of common as well as uncommon side effects are provided later in this guide.

Checking for:

- any changes that are contraindications; in this case, the woman should be advised to see her doctor¹
- any change in the woman's health status (no new conditions and no worsening of existing conditions) since the last time she saw her doctor for a prescription or the last time she was provided with Hana; for any changes that are warnings, the woman should be advised to see her doctor¹

If a woman is referred to her doctor to check any contraindications or warnings to determine suitability for Hana, she should be advised that if her suitability is confirmed, she can return to the pharmacy to obtain Hana.

Pharmacy supply aid reminder	Guidance on pharmacist action
Check for changes in vaginal bleeding (e.g. heavy or prolonged bleeding, or bleeding following sexual intercourse)	 Checking for changes to bleeding pattern or unusual bleeding. Hana primarily acts by inhibiting ovulation, so it is normal for the woman to experience some change in her bleeding patterns¹ If periods are more frequent and this is bothersome for the woman, she should be referred to her doctor for an alternative method of contraception¹ If periods differ from those expected with Hana or are unusually heavy, she should be referred to her doctor for investigation to rule out any underlying pathology¹ If she repeatedly has bleeding after sex, she should be referred to her doctor for investigation (e.g. for cervical cancer)¹
Check for changes to regular medications or herbal remedies, or use of other medication	Checking whether there are any new potential drug interactions, as some may affect the clearance of contraceptive hormones, and may have an impact on the contraceptive efficacy of Hana. ¹ Refer back to page 14 for the list of medicines impacting CYP enzymes; read the SmPC for a full list of drug interactions.

REPEAT SUPPLY OR CHANGING SUPPLY excluding pregnancy

Before starting a new pack of Hana, a woman should be reasonably certain that she is not pregnant.¹

If in doubt, particularly if she has not been using Hana consistently and correctly, she should be advised that there is a chance that she may be pregnant.¹ Hana can be supplied, but she should be advised to:1

- do a pregnancy test at least 3 weeks after the last episode of unprotected sex
- continue taking Hana until the result of the pregnancy test is available
- stop Hana immediately and see a doctor if the pregnancy test is positive

INFORMATION ON QUICK STARTING HANA

- Quick starting is the term used to describe immediate initiation of a contraceptive method at the time a woman requests it rather than waiting for the start of her next menstrual period¹³
- Quick starting is outside the approved use of Hana and its SmPC so cannot be recommended for pharmacy supply, although it is common practice in family planning settings and may be appropriate for some women or situations^{13,14}
 - For example, women who may be especially vulnerable to unplanned pregnancy if regular contraception is not started as soon as possible, or women who have required emergency contraception^{13,14}
 - Pharmacists may use their professional judgement and have a woman quick start Hana

Cons

Quick starting Hana after use of emergency contraception:

She can start Hana immediately after levonorgestrel (additional contraceptive measures for first 7 days)¹

She can start Hana no sooner than 5 days after ulipristal acetate (additional contraceptive measures for 5 days of waiting and for first 7 days of Hana use; i.e. 12 days in total)¹

Pros

- Reduces the time during which a woman is at risk of pregnancy¹³
 - Women who have taken emergency contraception or who have irregular menstrual cycles could have an even longer wait until the start of their next menstrual period¹³
- Prevents a woman from forgetting recommendations on correct usage of her contraception¹³
- Avoids diminishing enthusiasm for the method and use of a less reliable alternative method¹³

- Safety and efficacy of starting after day 5 of the menstrual cycle have not been established
- Additional contraceptive measures are required for the first 7 days of tablet taking¹
- Low risk that a woman is already pregnant, or that emergency contraception fails and she falls pregnant from recent unprotected sex, despite use of criteria for excluding pregnancy¹³
- Risk of unintentional exposure of a foetus to desogestrel has been shown to be low^{1,13}
- If pregnancy cannot be excluded prior to guick starting, a pregnancy test must be performed at least 3 weeks after the last episode of unprotected sex, including any episodes within the 7 days it takes for Hana to reach its maximum effectiveness^{13,14}

 Information on quick starting can be found in the Faculty of Sexual & Reproductive Healthcare (FSRH) Guideline on Quick Starting Contraception¹³ and the FSRH Guidance on Progestogen-only Contraception¹⁴

ADVICE FOR ALL WOMEN TAKING HANA: **HOW TO TAKE HANA**

It is important to give all women advice on how to take Hana, what to do if a dose is missed or in case of gastrointestinal disturbances, how to take Hana after emergency contraception, and what side effects to be aware of when taking Hana.

Remind the woman to read the patient information leaflet (PIL) carefully; all the information in the following section is in the PIL. You can also suggest that she saves the link to the PIL website.

How to take Hana and deal with missed doses or gastrointestinal disturbances

How to take Hana	 One tablet daily, taken a Once a pack is finished, break, regardless of blee 	sta
If a dose is missed	is missed by ≤12 hours: ¹ take the tablet immediately and take the next scheduled dose as usual; this could mean taking 2 tablets on the	If o mis take imn the dos cou 2 ta day are the
		Mis cyc pre she mis anc do
In case of vomiting within 3-4 hours of taking Hana	Take another tablet immed as usual ¹	diat
In case of severe or persistent gastrointestinal disturbances (vomiting or diarrhoea)	Continue taking tablets ev the gastrointestinal disturl have stopped ¹	

the same time every day 24 hours apart¹ tart the new pack the next day without a ling¹

one tablet is issed by >12 hours:¹

ke the tablet mediately and take e next scheduled ose as usual; this ould mean taking tablets on the same ay; extra precautions e recommended for e next 7 days

If more than one tablet has been missed:1

only one missed tablet should be taken immediately, and the next scheduled dose taken as usual: this could mean taking 2 tablets on the same day; extra precautions are recommended for the next 7 days

ssed tablets at any time in the menstrual cle can reduce the efficacy of Hana and risk egnancy, but missing a tablet in the first eek after starting Hana carries more risk;¹ if e had sex in the week before the tablets were issed, consider the possibility of pregnancy id, if appropriate, advise the woman to a pregnancy test; consider the need for nergency contraception for any missed pills¹

ately and take the next scheduled dose

ry day, but use extra precautions for as long as nces or vomiting last, and for 7 days after they How to take Hana after emergency contraception containing:

- levonorgestrel (synthetic progestogen)
- ulipristal acetate (selective progesterone receptor modulator)

If the woman is starting Hana

Wait until day 1 of her next period to start Hana; she should continue to use other precautions until this time¹

If quick starting or woman has taken emergency contraception due to missed Hana tablet(s)

Levonorgestrel:

take or resume Hana that same day and use additional contraceptive measures (abstinence or barrier methods) for the first 7 days of Hana use¹

Ulipristal acetate:

wait 5 days after taking ulipristal acetate before starting or restarting Hana.¹ Use additional contraceptive measures (abstinence or barrier methods) during the 5 days of waiting and for the first 7 days of Hana use (i.e. 12 days in total)¹

Remind every woman to read the PIL carefully before taking Hana.

ADVICE FOR ALL WOMEN TAKING HANA: WHEN TO SEEK MEDICAL ADVICE

There are some situations that you should be aware of in case a woman reports these symptoms. These situations require immediate medical attention.

Symptom/warning sign

Pelvic pain with either vaginal bleeding/ spotting or amenorrhoea¹

Pain or swelling in either leg, heavy ache, warm skin at the site, red skin at the back of the leg below the knee^{4,15}

Breathlessness, unexplained chest pain, unusual cough, coughing up blood^{4,15}

Yellowing of the skin or whites of the eyes, dark urine, other signs and symptoms of liver disorders⁴

Possible cause

Ectopic pregnancy

As with all women of reproductive age, ectopic pregnancy should be considered a possibility if the woman develops these symptoms, particularly if Hana has been used inconsistently or incorrectly making pregnancy more likely;¹ the woman may not know she is pregnant as she may not have missed a period, or have mistakenly thought she had her period because of bleeding caused by either Hana or the ectopic pregnancy; these symptoms should prompt you to refer the woman for immediate medical attention regardless of whether her use of Hana has been correct¹

Blood clot in the leg/deep vein thrombosis (DVT)

Pulmonary embolism

Jaundice, other liver disorders, liver cancer

There are also some non-urgent warning signs that you should be aware of in case a woman reports these symptoms while using Hana. All require medical assessment and are listed in the PIL.

- Changes to the breasts, including breast discharge, breast pain or feeling a lump^{1,4}
- Changes in bleeding patterns are common with Hana and women may be happy to accommodate them.^{1,4} However, there are some specific types of bleeding that might have an underlying pathology; if women experience the following changes in their bleeding pattern during use, they should be referred to their doctor for investigation:¹
 - bleeding changes that differ from those which would be expected with Hana or bleeding that is unusually heavy
 - repeated vaginal bleeding after sex
- Mood changes and depression are known side effects of hormonal contraceptive use¹
 - Depression can be serious, and women should see their doctor if they experience mood changes or symptoms of depression¹
- Sustained increase in blood pressure (sustained hypertension) or high blood pressure that is not adequately responding to antihypertensive therapy as incidental findings (pharmacists are not expected to check/monitor blood pressure prior to or during supply)¹

These situations may arise during use of Hana, but are not necessarily related to Hana.

Remind every woman to read the PIL carefully before taking Hana.

ADVICE FOR ALL WOMEN TAKING HANA: WHAT SIDE EFFECTS TO BE AWARE OF

Hana is generally well-tolerated and serious side effects are rare.^{1,4}

Below are lists of the commonly (occurring in at least 1 woman per 100) and uncommonly reported (at least 1 woman per 1000) side effects with Hana. Please read the SmPC for full details of side effects.

Common ¹	
Altered mood, depressed mood	
Decreased libido	
Headache	
Nausea	
Acne	
Breast pain	
Irregular menstruation or amenorrhoea	
Increased body weight	

Irregular bleeding

The most commonly reported side effect is irregular bleeding, which has been reported by up to 50% of women using Hana.¹

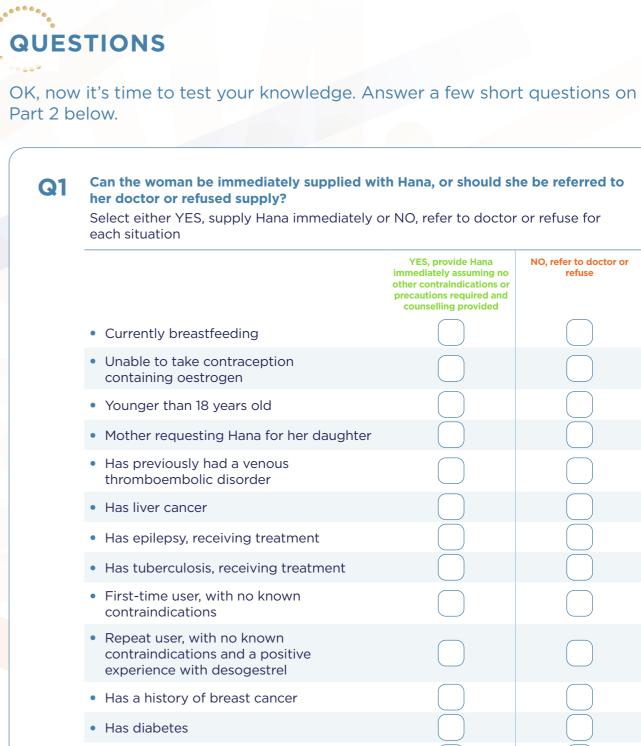
- Bleeding may become more frequent in 20-30% of women and less frequent or totally absent in 20%¹
- Bleeding episodes tend to become less frequent and settle after a few months of treatment¹

Remind every woman to read the PIL carefully before taking Hana.

Uncommon ¹
Vaginal infection
Contact lens intolerance
Vomiting
Alopecia
Dysmenorrhoea
Ovarian cyst
Fatigue

ADVICE FOR ALL WOMEN: ONGOING SEXUAL **HEALTH MANAGEMENT**

Sexually transmitted infections	 Remind the woman that only condoms protect against sexually transmitted infections⁴ Advise the woman to go for a check-up at a sexual health clinic as soon as she can if she is worried she has a sexually transmitted infection; many of these infections, including HIV (AIDS), have no symptoms so the woman can only be certain if she gets tested¹
Cervical screening	 Advise the woman to continue to have regular smear tests to check the health of cells in the cervix¹
Breast screen/check	 Advise women aged 50 years and above to attend regular breast screening to detect early signs of breast cancer¹ Advise women aged below 50 years to report any lump or change in their breasts to their doctor¹
Emergency contraception	 Advise women to consider taking emergency contraception after unprotected sex, or if there has been a threat to the efficacy of their usual contraceptive method⁴
Further information on contraception and screening	 Refer women to https://www.nhs.uk for further information on all methods of contraception, emergency contraception or screening⁴



- Following an abortion
- Allergic to the active substance
- Allergic to the excipients (inactive substances)
- Previously using a contraceptive skin
- Undiagnosed vaginal bleeding after se
- Has a history of chloasma

Can the woman be immediately supplied with Hana, or should she be referred to

	YES, provide Hana immediately assuming no other contraindications or precautions required and counselling provided	NO, refer to doctor or refuse
hter		
patch		
ex		

Q2 How should Hana be taken? Select all that apply

- At the same time every day
- Hana can be started on the first day of menstrual bleeding without requiring additional precautions
- Once a pack is finished, wait one week until starting the new blister

Q3 What are the key safety messages for all women taking Hana? Select all that apply

- Change to the bleeding pattern is common and there is no need to return or to see your doctor in the first few months even if you are experiencing heavy or extended bleeding
- Change to bleeding pattern is common and it is likely to settle in the first few months; however, return to the pharmacy or see your doctor if the bleeding is unacceptable
- If you forget to take a tablet and it has been more than 12 hours, take that tablet immediately and then take the next scheduled dose as usual. There is no need to use extra precautions
- If you forget to take a tablet and it has been more than 12 hours, take that tablet immediately and then take the next scheduled dose as usual. Remember to use extra precautions for the next 7 days, and consider the need for emergency contraception
- There is no need for extra precautions if you remember to take the forgotten tablet within 12 hours of when you usually take it

Turn to page 63 to check your answers.

Par 3

LEARNING OUTCOMES AT A GLANCE

Consolidate knowledge of when supply of Hana is/is not appropriate

Know what questions to ask women when discussing Hana in different supply situations

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ASSESSING SUITABILITY AND **PROVIDING ADVICE IN PHARMACY**

Corresponding animated videos are available online, which you can access here: https://info.hanapharmacist.co.uk/animations.





HARMACY



Hi, I'm thinking of going on the pill, I've heard you don't need a prescription.

Although you don't need a prescription, I just need to ask you a few questions, to make sure it's appropriate for you.

Can I just check what year you were born in?



Of course, I was born in the year 2000.

Perfect. We can chat here, or would you like to go somewhere a little quieter?



Somewhere a little quieter please.

OK, the pill you're referring to is called Hana. However, there are other contraceptive options available to you, are you aware of them?





Sounds like you've done your research. Do you have any current or past medical problems?



No, I'm generally well.

No, definitely not on both counts.

OK, so just to help us confirm that, another question or two. Have you had sex since the start of your last period?

I haven't actually, my period started 3 days ago.

OK that's good, I think we can safely say you're not pregnant. Hana shouldn't be used if you are, which is why it was



That makes sense.

No, nothing.

1. A WOMAN WHO HAS NEVER USED ANY FORM OF CONTRACEPTION

Yes, I had a look online to see what the options were. This contraceptive seems to tick all the boxes for me.

> Is there any chance you could be pregnant, or have you been pregnant recently?

important to check.

Are you taking any sort of medicine, including herbal remedies?



What about allergies, do you have any?

1. A WOMAN WHO HAS NEVER USED ANY FORM OF CONTRACEPTION

No, nothing to report there either.



Do you bleed between your periods, or after you have sex?



They're normal, just a bit painful, but I don't bleed at other times.



OK, I have no concerns so can sell you a 3-month supply to get you started, and you can see how you get on with it before we provide you with more. I'd encourage you to let your doctor know that you've got Hana from us though, the next time you see them, just so they're upto-date with your medicines.

Because of the way Hana works, your periods may no longer be as regular as usual and you might experience some spotting in between periods, but this usually settles after a few months.

If the bleeding is unacceptable to you, consider going to see your doctor to discuss an alternative method of contraception.

If you bleed after sex, or if you have especially heavy or prolonged bleeding, you should go and see your doctor to get it checked out.



OK, will do.

The same if you find any lumps or changes to your breasts, or have any mood changes.

Talk to your doctor about them.

There are a couple of things you need to look out for, even though they may not be related to the pill. The leaflet in the pack explains everything so please make sure you read it carefully.



That all seems clear. When can I get started?



Because your period started less than 5 days ago, you can actually get started with Hana today.

You'll need to use an extra barrier method, like condoms, for the first 7 days though.

It's important to take one pill every day.

The pack will help you keep track, as it's labelled with the days of the week as well as arrows to guide you.

So if you start the pack on a Wednesday, take a pill marked with Wednesday and follow the arrows.

And take the pills at the same time every day, it doesn't matter what time though. Make it a routine, download a reminder app, set an alarm or take it while doing something you do at the same time every day, like with your morning tea or coffee or when you brush your teeth before going to bed.

When you have finished a pack, start the new pack the next day without a break, whether or not you start bleeding.

If you're less than 12 hours late taking your pill, just take it as soon as you remember within those 12 hours, and take the next one as usual, even if that might mean taking 2 pills on the same day.

If you're more than 12 hours late, take the missed pill as soon as you remember and take the next one as usual too, again even if that might mean taking 2 pills on the same day, but you will need to use extra precautions for seven days.

The same goes if you miss more than one tablet, take just one of the missed tablets though, but again use extra precautions for seven days.

This information is all in the leaflet, along with guidance on what to do if you experience any vomiting or diarrhoea. There is also some advice in the leaflet about what you can do to protect against sexually transmitted infections, as well as about keeping up to date with your smear tests and being aware of any changes to your breasts and checking in with your doctor if you do notice anything unusual, all of which helps you to stay healthy.



That all sounds good, thank you.



1. A WOMAN WHO HAS NEVER USED ANY FORM OF CONTRACEPTION





2.A WOMAN SWITCHING FROM COMBINED ORAL CONTRACEPTION



Hi, I've almost finished my contraceptive pills. I had a chat with the nurse at my doctor's surgery on the phone a couple of weeks ago about all the options out there, and having thought it all through, I've decided I want to change onto the pill you can have without prescription. I think it's called Hana, can I get it from you?

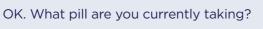


Yes, certainly, I'm happy to help. I'd just like to make sure it's appropriate for you, and you know how to take it.

Are you happy to chat here, or would you prefer to go somewhere quieter?

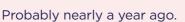


Here's fine.



It's the one you take for 21 days, then have a week off.

And when did you last see your doctor?



Have you had any changes in your health since then?

No, I'm absolutely fine.

Good to hear. I know you're on the pill now, but have you been pregnant recently?

No, I've been on the pill for a few years now.

And in the last month, have you missed any pills?



No. You have to take this pill every single day without any breaks, 365 days a year. When you have finished a pack, start the new pack the next day without a break, whether or not you start bleeding. Like your current pill, it is also very important that you take this pill at the same time every day. It doesn't matter what time of day, but it can be helpful to link it to part of your daily routine. You could think about taking it at

If you're less than 12 hours late taking your pill, just take it as soon as you remember and take the next one as usual, even if that might mean taking 2 pills on the same day. If you're more than 12 hours late, take the missed pill as soon as you remember and take the next one as usual too, again even if that might mean taking 2 pills on the same day, but you will need to use extra precautions for 7 days. The same goes if you miss more than one tablet, take just one of the missed tablets though,

2.A WOMAN SWITCHING FROM COMBINED ORAL CONTRACEPTION

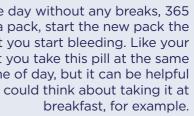
Any allergies?

between your periods or after sex?



with more. I know you've spoken to the nurse about the possibility of changing contraception, but do just confirm with your doctor's surgery that you have indeed switched onto Hana.

OK. So do I just take Hana in the same way as my old pill?







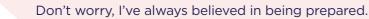


but again use extra precautions for seven days. Then there's more guidance in the leaflet in the pack on what to do if you experience any vomiting or diarrhoea.

OK great, when can I start taking it?



You have two options. You can start taking this pill the day after you finish your current pack. Although you won't have the usual 7-day break, you will still experience your period as normal. Alternatively, you can finish your current pack, have the usual 7-day break and then start taking this pill the next day. If you choose the second option you must be sure to use extra precautions for 7 days as you won't yet be protected. Of course, we can help with that as well.





Also because of the way Hana works, your periods may not be as regular as usual and you might experience some spotting in between periods, but this usually settles after a few months.

If the bleeding is unacceptable to you, consider going to see your doctor to discuss an alternative method of contraception. If you bleed after sex, you should go and see your doctor to get it checked out.

Also, just as with your current pill, be aware of any changes to your breasts or any changes in your mood and talk to your doctor if anything is different from usual.

Yes, I will remember that.

The leaflet in the pack has all the information you need, including about how to protect yourself from sexually transmitted infections, so please read it carefully, but do come back if you have any questions.

OK, great, thank you.

My final piece of advice: it is really important to keep up to date with your smear tests to stay healthy.

3.AN ADOLESCENT WOMAN •• WHO HAS NEVER USED ANY FORM OF CONTRACEPTION



Hi, I'd like to go on the pill please, I've heard I can just get it from you.

That's right, we do have a pill available that you can purchase without a prescription. I do just need to ask you a few questions, to make sure

> We can do that here, or would you prefer to go somewhere a little quieter?



Please can we go somewhere a bit guieter?

There's a variety of contraceptive options for you to choose from, not just the pill you've asked about. Do you know about them?





l'm 15.

OK, have you spoken to anyone about going on the pill?



Well, my boyfriend knows I'm here. We spoke about it and decided the pill was the best option.

What about your parents, have you spoken to them about it?



There's no way I'd tell my parents.

OK. I could speak to them on your behalf if you'd prefer?











Yes, I looked online and this seems the most effective option I can get without going to my doctor. You see, he lives on our road, and..., well...

OK. Can I just check how old you are please?

3.AN ADOLESCENT WOMAN WHO HAS NEVER USED ANY FORM OF CONTRACEPTION



No thank you, I really don't want them knowing that I've started having sex.

OK, I understand. You mentioned your boyfriend, is he 15 too?



Yes, he's in my year at school, we've been going out for a year now.

What about medical problems, do you have any, or have you had any in the past?



No, I'm fit and well, always have been.

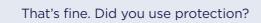
Is there any chance you could be pregnant, or have you been pregnant recently?



No, definitely not.

OK, so just to help us check that, another question or two if that's OK. Have you had sex since the start of your last period?

Yes, I have.





Yes, we've been using condoms.

OK that's good, it means we can assume you're not pregnant. It was important to check because Hana shouldn't be used if you're pregnant, which is why you'll now need to wait until the first day of your next period before starting so we can be sure.

Are you taking any sort of medicine, including herbal ones?

Just something to kick a cold or headache when they happen.





No, none.



I get period pains like everyone else, but no bleeding at other times.

OK, I'm happy to give you a 3-month supply, and you can see how you get on with it before we give you another 3-month supply and so on. I really would encourage you to let your doctor know that you're using Hana if you feel comfortable doing so, just so that they're aware of all your medicines.

You should know that because of the way this pill works, your periods may not be as regular as normal and you might have some spotting in between your periods, but this usually settles down after a few months.

If you find the bleeding unacceptable, please do come back and see me, and we can think about next steps. The same applies if you bleed after sex, or if you have especially heavy or prolonged bleeding, we can think about getting it checked out. Of course you can go and see your doctor too.

OK.

The same again if you happen to notice any unusual changes to your breasts, like lumps, or changes to your general mood. Come back to see me, or talk to your doctor if you prefer.

There are a couple of other things you need to be aware of, even though they may not be related to the pill. The leaflet in the pack explains everything so please read it carefully.

You should continue taking your Hana until your doctor or I tell you to stop though, just to make sure you don't get pregnant.



All clear. When can I start?

3. AN ADOLESCENT WOMAN WHO HAS NEVER USED ANY FORM OF CONTRACEPTION











Start this pack on the first day of your period. If your period doesn't start when you expect it to, take a pregnancy test or see your doctor. If the test is negative, you can start the pill on the first day of your next period. It's important to take one pill every day. The pack will help you keep track, as it's labelled with the days of the week as well as arrows to guide you. So if you start the pack on a Monday, take a pill marked with Monday and follow the arrows. And take the pills at the same time every day. Make it a routine, maybe take it while doing something you do at the same time every day, like with your morning tea or coffee or when you brush your teeth before going to bed. When you've finished a pack, start the new pack the next day without a break, whether or not you start bleeding.

Make sense so far?



Yes, that all makes sense.

If you happen to miss your pill, if you're less than 12 hours late, just take it as soon as you remember within those 12 hours, and take the next one as usual, even if that might mean taking 2 pills on the same day. If you're more than 12 hours late, take the missed pill as soon as you remember and take the next one as usual too, again even if that might mean taking 2 pills on the same day, but you'll need to use a condom or other protection for seven days. The same goes if you miss more than one tablet, take just one of the missed tablets though, but again use a condom for seven days.

Still making sense?



Yes, that's all fine.



Everything I've told you is in the leaflet though, along with guidance on what to do if you have any vomiting or diarrhoea. Hana won't protect you against STIs, so there's also some advice in there about what you can do to protect against them. It also goes over being aware of any changes to your breasts and checking in with me or your doctor if you notice anything unusual. And you know you can always come back and see me if you have any questions or concerns at all.



Thank you!

4.A WOMAN WHO HAS PREVIOUSLY PURCHASED HANA FROM A PHARMACY



I'm happy to help. I just need to ask a few questions to make sure it's still appropriate for you. Are you happy to talk here or would you



Here is fine.

Since you got your last supply from a pharmacy, have you had any illness, started taking any new medications, even herbal remedies, or



No, no and no.



is great. Is that normal?

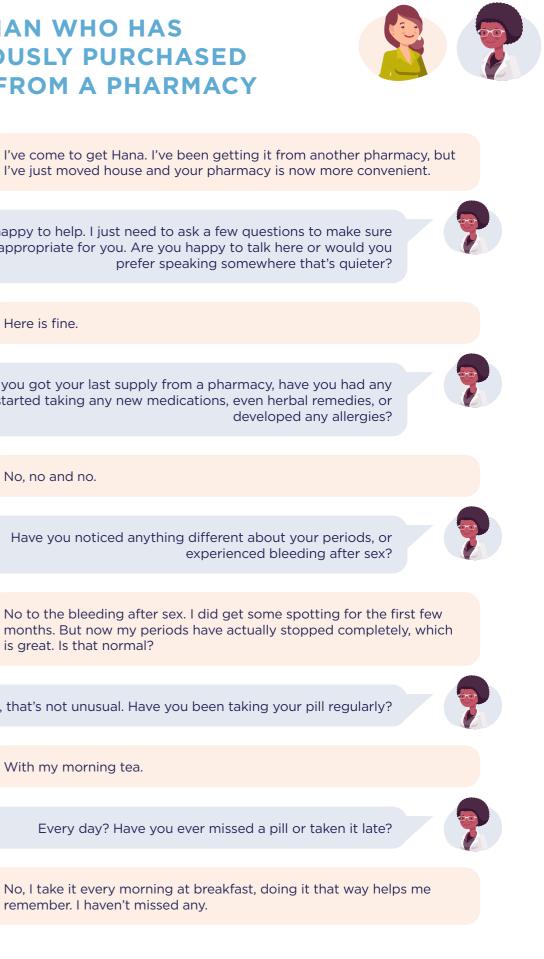
Well, that's not unusual. Have you been taking your pill regularly?



With my morning tea.



remember. I haven't missed any.



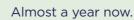




Hi, I'm hoping you can help me. I've been using desogestrel for a while now. I usually get a prescription, but now I've heard I can just get it from you?

Yes, that's true, I'm happy to help. Follow me to our consultation room, as I do need to ask you a few questions first.





Has anything changed since your last prescription? Have you had any illnesses, started taking any new medicines or herbal remedies, or developed any allergies?



Well, apart from catching the odd cold or two, I've been fine, so no nothing's changed.

How have you been getting on with desogestrel, have you had any problems with bleeding after sex or especially heavy or prolonged bleeding?

I got some spotting for a couple of months, but that's stopped now.

Have you missed any pills, or have you got into a good routine



It was difficult at the beginning, but I'm now used to taking them every day and haven't missed a pill for a couple of months I think.

Good, that's OK, periods can stop with this pill - it's not unusual and it's not harmful.

It was important to check whether you'd missed any pills to rule out the possibility of pregnancy.

Just to remind you though, it's worth reading the leaflet inside the pack again to refresh your memory.



There's information in the leaflet about general health too, around sexually transmitted infections, smear tests and being aware of any changes to the breasts.

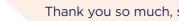
In case you haven't done so already, please do tell your doctor that you're getting Hana from the pharmacy, just so they have the full picture of your medicines.

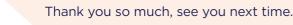
OK, how many months' supply would you like? Is 3 months OK, or would you like more?

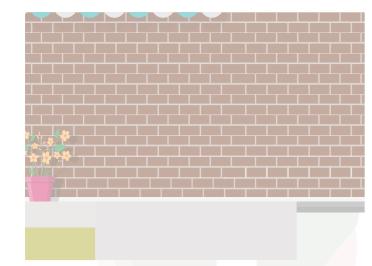


Could I have 6 months' supply please?

Here you go. Remember to keep on taking it at the same time every day, with no breaks between packs.













How long have you been using desogestrel?



with them?





5.A WOMAN WHO HAS PREVIOUSLY BEEN PRESCRIBED DESOGESTREL BY HER DOCTOR

Perfect. That helps us rule out the possibility of pregnancy. But don't forget, you need to take each pill at the same time every day with no break, so start the next pack as soon as you finish your current pack. OK, how many months' supply would you like?

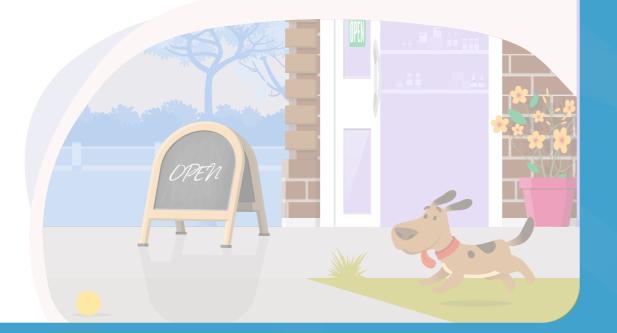
> Yes, I remember about the 12-hour rule. I take it every evening as I'm brushing my teeth. I'm travelling a lot these days, so if I can have a year's supply, that would be great.



Yes, of course, 12 months is fine. Do let your doctor know that you're now getting your desogestrel from the pharmacy rather than on prescription the next time you see them. Then make sure you read the leaflet in the pack, there's some useful information in it. And I'm sure I don't need to remind you that the pill won't protect against sexually transmitted infections so if you're concerned, use condoms and get checked at the sexual health clinic if you think you might have picked one up. Also be aware of any changes to your breasts and see your doctor if you notice anything unusual, and stay up to date with your smear tests. Of course, if you have any questions or any problems, just pop back in and we can sort them out.



Thank you so much, see you in another year.



6.A WOMAN WHO HAS PREVIOUSLY PURCHASED HANA FROM A PHARMACY AND HAS **EXPERIENCED BLEEDING AFTER SEX**

important and what I should do about it.

Yes, pretty much. Could it be the Hana that's causing it?

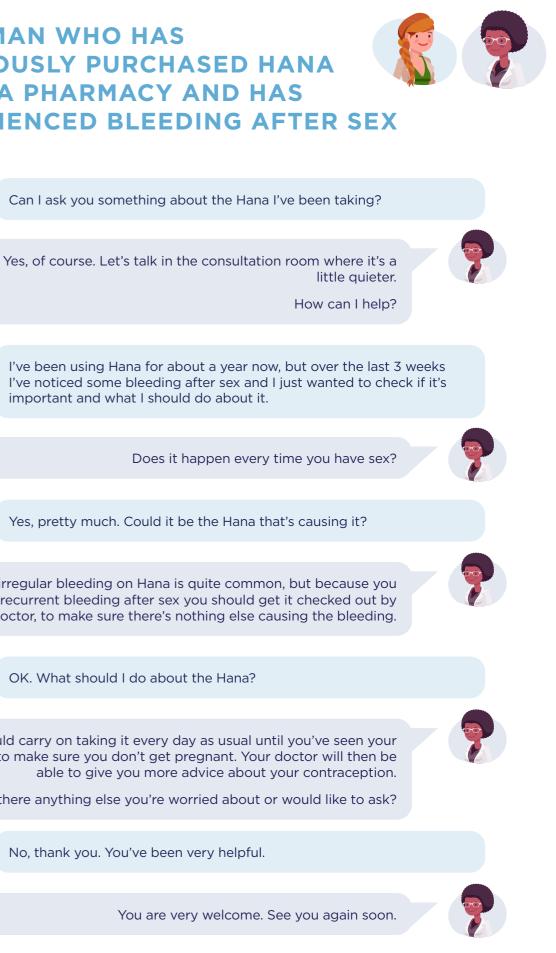
Well irregular bleeding on Hana is quite common, but because you have recurrent bleeding after sex you should get it checked out by your doctor, to make sure there's nothing else causing the bleeding.

OK. What should I do about the Hana?

You should carry on taking it every day as usual until you've seen your doctor, to make sure you don't get pregnant. Your doctor will then be

Is there anything else you're worried about or would like to ask?

No, thank you. You've been very helpful.



7. A WOMAN WHO HAS NEVER **USED HANA BEFORE AND WHO** HAS A HISTORY OF HEPATITIS



Hi, I'm thinking of going on the pill, I've heard you don't need a prescription.

Yes, that's right. But although you don't need a prescription, I do just need to ask you a few questions, to make sure it's appropriate for you.

We can chat here, or would you like to go somewhere a little quieter?



I'd prefer somewhere quieter please.

OK, can I just ask why you're interested in this pill specifically? Have you looked at the options?



If I understand correctly, this is the only pill available without a prescription, and popping to the pharmacy would just fit much better with my lifestyle, plus it seems to be effective.

Absolutely, and I completely understand. OK, do you have any current or past medical problems?



I did have hepatitis 10 years ago.

Can you tell me a little more about that? How is your liver now?

I think I'm fine now.

Have you had any other medical problems in the past?

No, that's it.



As you've had hepatitis in the past, you do need to see your doctor first and check that they're happy for you to take Hana.

If they say it's fine, do come back to the pharmacy and we'll be very happy to supply you with Hana.



I know, but because it was your liver that was affected, it's important for your doctor, who will have access to all your liver tests, to decide whether Hana is appropriate for you.



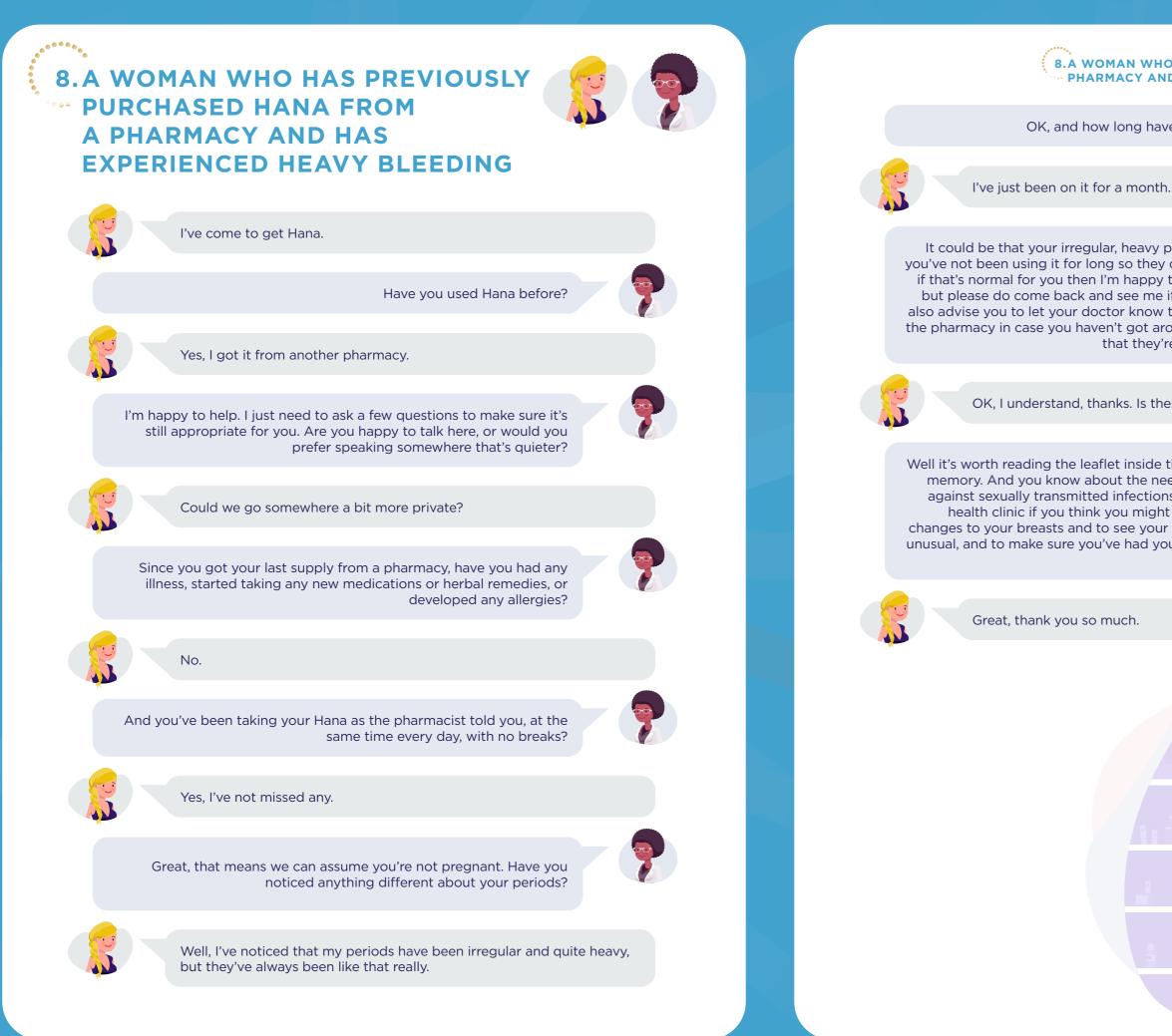
Alright, I'll do that. Thank you for your help.



7. A WOMAN WHO HAS NEVER USED HANA BEFORE AND WHO HAS A HISTORY OF HEPATITIS

Oh that's a nuisance. Is it really necessary, I've been fine for ages?

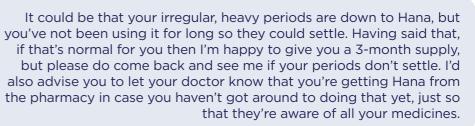
You're welcome. Hopefully we'll see you again soon!



8.A WOMAN WHO HAS PREVIOUSLY PURCHASED HANA FROM A PHARMACY AND HAS EXPERIENCED HEAVY BLEEDING

OK, and how long have you been taking Hana now?





OK, I understand, thanks. Is there anything else I need to know?



Well it's worth reading the leaflet inside the pack again to refresh your memory. And you know about the need to use condoms to protect against sexually transmitted infections and check-ups at the sexual health clinic if you think you might have one, to be aware of any changes to your breasts and to see your doctor if you notice anything unusual, and to make sure you've had your smear test within the last 3 years, so you're all set.





You have finished the Pharmacy guide. **Download a printable version of the guide here:** https://info.hanapharmacist.co.uk/guide.

To assess your knowledge of Hana and how to supply it in pharmacy and receive your CPD certificate, we invite you to answer a series of questions and give your opinion on some case studies online.

There are 15 guestions and 5 case studies. You will have access to the SmPC whilst completing the exercise - as you would in your pharmacy.

Scores of 100% will earn a certificate that can be used for CPD and to fulfil Clinical Governance requirements. You can retake the exercise if you do not succeed the first time.

Get started with the exercise here: https://info.hanapharmacist.co.uk/assessment.



ANSWERS TO 1 AND 2 QUESTIONS **ANSWERS Q1** How does Hana work? Increasing viscosity of the cervical mu · Preventing the fertilised egg from imp • Delaying ovulation • Inhibiting ovulation Hana works primarily by inhibiting ovulation cervical mucus, to create a barrier to stop spe **Q2** How should Hana be taken to maximise

- For 21 days with a 7-day break at the
- At the same time each day
- · Continuously. Every day without a bre
- Every day, can be at a different time e
- Hana should be taken every day with no br
- Hana should be taken at the same time eac maximum contraceptive effect

JCUS	
planting in the womb	×
	×
	\checkmark
and also increasing the viscosity o erm from entering the uterus	f the

effectiveness?	
end of the pack	×
eak between packs	\checkmark
each day	\mathbf{X}
reak between packs ch day, or within 12 hours, to maintair	n the
	,

Q3 In which of these situations should Hana NOT be used?

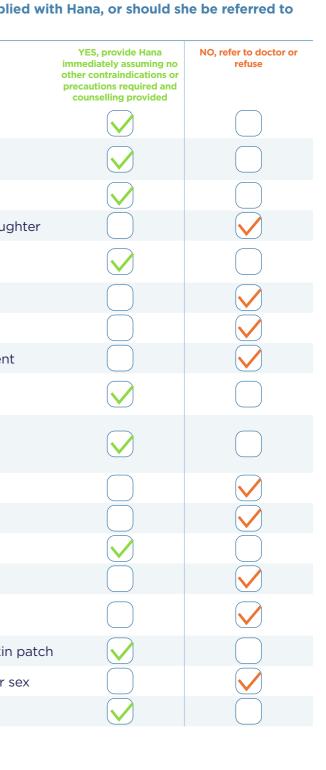
	CAN be used	Should NOT be used
Pregnancy		\checkmark
Breastfeeding	\checkmark	
• Aged <18 years	\checkmark	
 A current blood clot in the legs (venous thrombosis) or lungs (pulmonary embolism) 		\checkmark
 Severe liver disorders where the liver function values have not returned to normal 		\checkmark
• Current sex-steroid sensitive malignancies such as certain types of breast cancer		\checkmark
Allergy to desogestrel		\checkmark
Lactose intolerance		\checkmark
No previous pregnancy	\checkmark	
Unable to take oestrogens	\checkmark	
 A blood clot in the legs (venous thrombosis) or lungs (pulmonary embolism) in the past 		

Which of the following medicines or herbal remedies can reduce the **Q4** effectiveness of Hana?

Phenytoin		
Paracetamol	×	
Rifampicin		
• Bosentan		
• St. John's Wort		
Efavirenz		
Ibuprofen	×	
Carbamazepine		
Ulipristal acetate		

2	ANSWERS
Q1	Can the woman be immediately supp her doctor or refused supply?
	Currently breastfeeding

- Currently breastfeeding
- Unable to take contraception containing oestrogen
- Younger than 18 years old
- Mother requesting Hana for her daughter
- Has previously had a venous thromboembolic disorder
- Has liver cancer
- Has epilepsy, receiving treatment
- Has tuberculosis, receiving treatment
- First-time user, with no known contraindications
- Repeat user, with no known contraindications and a positive experience with desogestrel
- Has a history of breast cancer
- Has diabetes
- Following an abortion
- Allergic to the active substance
- Allergic to the excipients (inactive substances)
- Previously using a contraceptive skin patch
- Undiagnosed vaginal bleeding after sex
- Has a history of chloasma



Q2 How should Hana be taken?

- At the same time every day
- Hana can be started on the first day of menstrual bleeding without requiring additional precautions

X

 (\mathbf{X})

X

- Once a pack is finished, wait one week until starting the new blister
- Hana should be taken at the same time every day (or within 12 hours of the time the tablet is due) to maintain the maximum contraceptive effect
- Hana can and should be taken on the first day of menstrual bleeding (day 1), in which case no additional precautions are needed
- Hana should be taken every day with no break between packs

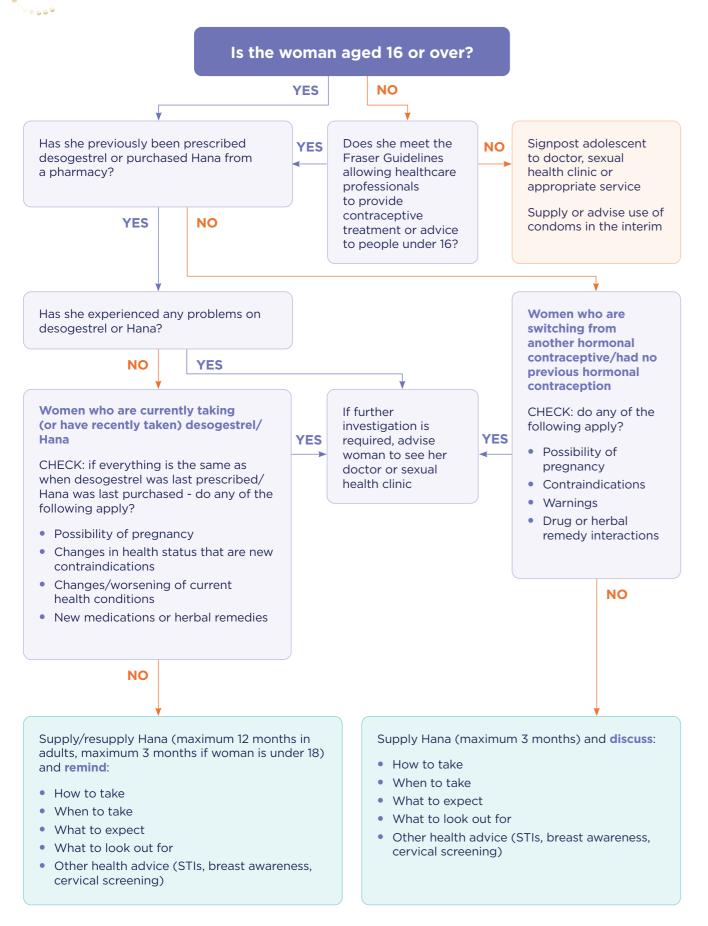
Q3 What are the key safety messages for all women taking Hana?

- Change to the bleeding pattern is common and there is no need to return or to see your doctor in the first few months even if you are experiencing heavy or extended bleeding
- Change to bleeding pattern is common and it is likely to settle in the first few months; however, return to the pharmacy or see your doctor if the bleeding is unacceptable
- If you forget to take a tablet and it has been more than 12 hours, take that tablet immediately and then take the next scheduled dose as usual. There is no need to use extra precautions
- If you forget to take a tablet and it has been more than 12 hours, take that tablet immediately and then take the next scheduled dose as usual. Remember to use extra precautions for the next 7 days, and consider the need for emergency contraception
- There is no need for extra precautions if you remember to take the forgotten tablet within 12 hours of when you usually take it
- 50% of women will experience change to bleeding patterns, but it is important for the woman to come back or to see her doctor if the bleeding pattern is unacceptable
- If a woman forgets to take a tablet and it has been less than 12 hours, that tablet should be taken immediately, and the next scheduled dose as usual; no need for extra precautions (contraceptive protection of Hana is only reduced if more than 12 hours have elapsed since the next tablet should have been taken - 12-hour window)
- If a woman forgets to take a tablet and it has been more than 12 hours, that tablet should be taken immediately, and the next scheduled dose as usual (even if this means the woman takes two tablets in one day); extra precautions should be used for the next 7 days, and the need for emergency contraception considered

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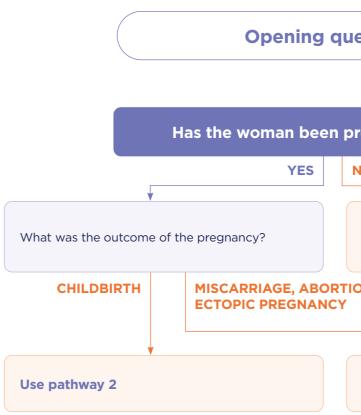
APPENDIX 1: PHARMACY SUPPLY ALGORITHM



APPENDIX 2: PREGNANCY EXCLUSION TOOL

This Pregnancy exclusion tool is designed to assist you with your consultations with women requesting a first-time supply of Hana in pharmacy, detailing questions to ask and responses to give, for women who have not recently been pregnant, have delivered or have had a miscarriage, abortion or ectopic pregnancy. Use of this material is optional, and you should use your professional judgement to decide when and how to use it.

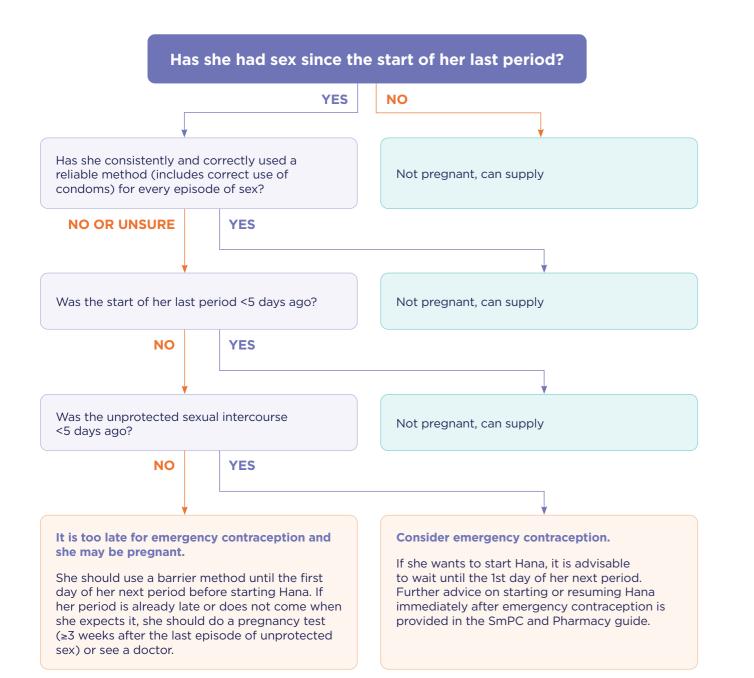
Use the opening questions to determine which pathway to use.



uestions	
pregnant recently?	
NO	
Use pathway 1	
TION OR Y	
Use pathway 3	

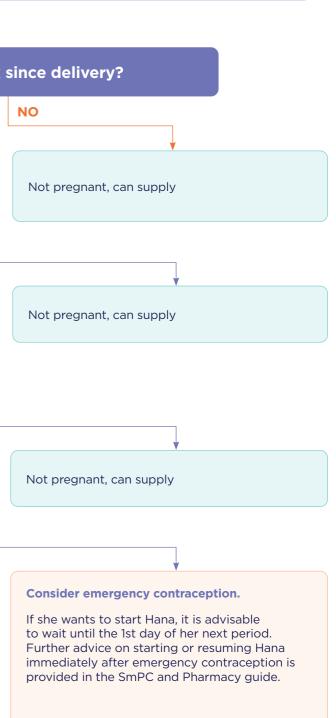
Pathway 1: women who have not recently been pregnant¹

Pathway 2: women who have <u>delivered</u>¹



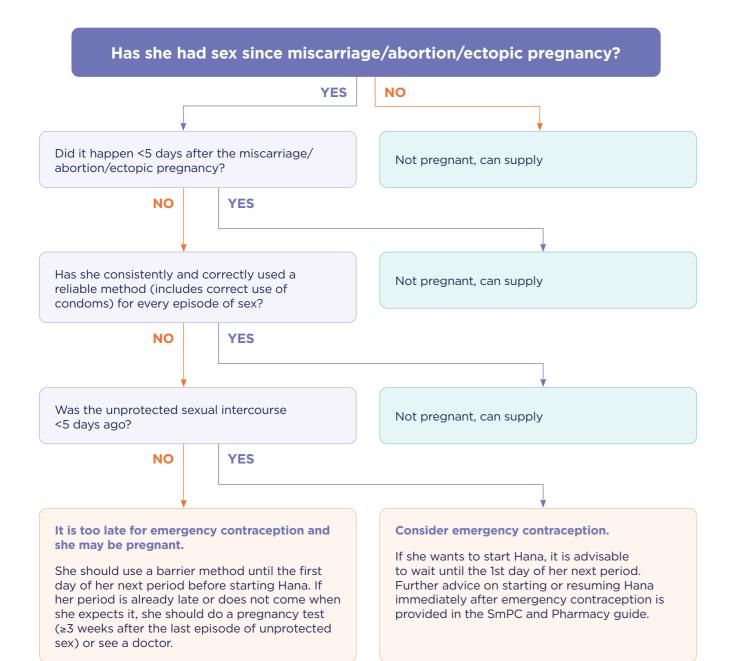
Has she had sex si		
	YES	
,	•	
When did she deliver?	?	
≥21 DAYS	<21 DAYS	
Is she fully breastfeeding (if applicable), amenorrhoeic and <6 months postpartum OR has she consistently and correctly used a reliable method (includes correct use of condoms) for every episode of sex?		
NO	YES	
Was the unprotected sexual intercourse <5 days ago?		
NO	YES	
It is too late for emerg she may be pregnant.	♥ rgency contraception and	
day of her next period her period is already la she expects it, she sho	tier method until the first d before starting Hana. If late or does not come when ould do a pregnancy test st episode of unprotected	

sex) or see a doctor.



69

Pathway 3: women who have had a <u>miscarriage</u>, <u>abortion</u> or <u>ectopic pregnancy¹</u>





Hana 75 microgram film coated tablets (desogestrel)

Indication: Hana 75 microgram film coated tablets contains desogestrel and is indicated for oral contraception in women of childbearing age to prevent pregnancy. Refer to SmPC for further prescribing information. Dosage and Administration: One tablet taken orally. Must be taken at same time every day, always 24h interval between 2 tablets. First tablet should be taken on day 1 of menstrual bleeding, can be started on days 2-5, but barrier method recommended for first 7 days of tablet-taking. Thereafter one tablet daily (continuously) without taking any notice of possible bleeding. When pack of pills is finished, a new pack should be started directly the day after the previous one. Pre-existing bleeding abnormalities such as oligomenorrhoea and amenorrhoea should be investigated before starting Hana. Refer to SmPC for full directions on how to prevent pregnancy. Contraindications: Known or suspected sex-steroid sensitive malignancies. Women with breast cancer. Active venous thromboembolic disorder. Presence or history of severe hepatic disease (as long as liver function values have not returned to normal). Undiagnosed vaginal bleeding. Hypersensitivity to the active substance or excipients. Special warnings and Precautions: Exclude pregnancy before starting Hana. Before starting Hana, use reliable contraceptive method until first day of next period. Women should be advised if menstrual period does not come when expected, she may be pregnant, to do a pregnancy test or see a physician. Provided pregnancy test is negative she can start Hana on the first day of next period. Before starting a new pack of Hana, a woman should be certain she is not pregnant. Refer to SmPC for full directions. Refer to physician if any of the following conditions/ risk factors are present: breast cancer, hepatic disorders and disturbances of liver function, hypertension, thromboembolic disorders, changes in bleeding patterns, diabetes, psychiatric disorders, ectopic pregnancy, effect on bone mineral density, conditions reported during pregnancy or during sex steroid use, chloasma, reduced efficacy in event of missed tablets, does not protect against HIV (AIDS) or other sexually transmitted infections, contains lactose, refer to SmPC for full warning and precaution information. Interactions: refer to SmPC for full interaction information. Undesirable Effects: Always consult the SmPC before prescribing. Only the most common side effects and those which are rare but may be serious are listed below. Most commonly reported adverse reactions: bleeding irregularity headache, acne, mood changes, decreased libido, breast pain, nausea and weight increase, amenorrhoea, irregular menstruation. Rare: rash, urticaria, erythema nodosum. On rare occasions ectopic pregnancies reported, hypersensitivity reactions, breast discharge can occur. Aggravation of angioedema and/ or aggravation of hereditary angioedema may occur. In women using combined oral contraceptives a number of (serious) undesirable effects have been reported: venous thromboembolic disorders, arterial thromboembolic disorders, hormone-dependent tumours (e.g. liver tumours, breast cancer), and chloasma, breakthrough bleeding and/or contraceptive failure may result from interactions of other drugs (enzyme inducers) with hormonal contraceptives. Consult the SmPC in relation to other adverse reactions. Legal Category: P. Pack size: 28 tablets. Retail Price: £9,48 (1x28) £20,90 (3x28), MA Number: PL 17836/0015, MA Holder: Laboratoire HRA Pharma, 200 avenue de Paris, 92320 Chatillon, France. Marketed by: HRA Pharma UK & Ireland Ltd, Haines House, 21 John Street, Bloomsbury, London, WCIN 2BF. Additional information and full Prescribing Information is available on request from med.info.uk@hra-pharma.com

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov. uk/yellowcard. Adverse events should also be reported to HRA Pharma UK & Ireland Ltd on 0800 917 9548 or email med.info.uk@hra-pharma.com

Date of last revision of text: November 2020 Company Reference: PL 17836/0015

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