



Hana[®]

75 microgram film coated tablets

Desogestrel

Daily contraceptive without prescription

PHARMACY SUPPLY AID CHECKLIST

Product Information available within folder



Hana[®]



HRA Pharma UK and Ireland Limited | Haines House | 21 John Street | London | WC1N 2BF | United Kingdom

Date of preparation: November 2020 | UK/HANA/0002

REFERENCES

1. Faculty of Sexual & Reproductive Healthcare Clinical Guidance (FSRH). Contraceptive Choices for Young People. March 2010 (amended May 2019). Available at: <https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/>. Accessed: November 2020.
2. Hana (desogestrel) Summary of Product Characteristics, November 2020.
3. Hana (desogestrel) Patient Information Leaflet, November 2020.

PRODUCT INFORMATION

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 product 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, depressed mood, 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, WC1N 2BF. Additional information and full Product 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:** UK/HANA/0144

GUIDANCE ON USE

This Pharmacy supply aid checklist is designed to assist you with your consultations with women requesting Hana in pharmacy, allowing you to **check their suitability and provide appropriate advice**. Use of this material is optional, and you should use your professional judgement to decide when and how to use it.

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 her suitability for Hana to be checked, and to be supplied it if appropriate, while she evaluates other options.

Please **provide women who have never used desogestrel before or who have not used it for several months with a checklist to complete**. On return, refer to the question/s that the woman has answered to reveal a Red Box Answer. If only Green Box Answers are revealed, **supply Hana** and advise her how to start taking Hana.

FIRST-TIME SUPPLY - WOMEN WHO HAVE NEVER USED DESOGESTREL BEFORE OR WHO HAVE NOT USED IT FOR SEVERAL MONTHS

Checklist question	Pharmacist action
How old are you?	<p>If the woman is <u>under 16 years of age</u>, only supply Hana if she meets Fraser Guidelines i.e. you are satisfied that:¹</p> <ul style="list-style-type: none"> • she will understand the advice and what is involved • she cannot be persuaded to inform her parents, or allow you to do so • she is very likely to begin, or continue to have, sex without contraception <ul style="list-style-type: none"> • without contraceptive advice or treatment, her physical and/or mental health would suffer • her best interests require her to receive contraceptive advice or treatment with or without parental consent <p>If the woman is <u>under 18 years of age</u>, supply max 3 months of Hana.</p>
Is there any possibility that you may be pregnant?	<p><i>Consider referring to the Pregnancy exclusion tool included with this piece.</i></p> <p>Pregnancy can reasonably be excluded in women who have not recently been pregnant if the woman:²</p> <ul style="list-style-type: none"> • has not had unprotected sex since the start of last period, or • has been consistently and correctly using a reliable method of contraception (including condoms, when those have been used correctly for every episode of sex), or • has had unprotected sex but only between days 1 and 5 of menstrual cycle <p>Pregnancy can reasonably be excluded in women who have recently been pregnant following:²</p> <ul style="list-style-type: none"> • childbirth if the woman: <ul style="list-style-type: none"> ○ has not had unprotected sex since childbirth, or ○ has had unprotected sex but <21 days after childbirth, or ○ is fully breastfeeding, amenorrhoeic and <6 months postpartum • miscarriage, abortion or ectopic pregnancy if the woman: <ul style="list-style-type: none"> ○ has not had unprotected sex since miscarriage, abortion or ectopic pregnancy, or ○ has had unprotected sex but <5 days after miscarriage, abortion or ectopic pregnancy <p>If pregnancy can reasonably be excluded, supply Hana and refer to instructions for starting in below section.</p> <p>If pregnancy cannot reasonably be excluded:²</p> <ul style="list-style-type: none"> • start Hana on day 1 of next period with extra precautions (e.g. condom) until then, or on days 2-5 with extra precautions for another 7 days <ul style="list-style-type: none"> ○ if period is already late or not when expected: take pregnancy test (≥3 weeks after last episode of unprotected sex) or visit doctor ○ if the woman had unprotected sex <5 days ago: consider emergency contraception
Do you experience any bleeding between your periods or after sex?	<p>It is important to know the cause of any pre-existing vaginal bleeding abnormalities before starting Hana.²</p> <p>Do not supply Hana if vaginal bleeding has an unexplained cause; refer to doctor to exclude underlying pathology.²</p>

<p>Do you currently have or have you previously had any health conditions?</p> <p>(e.g. cancer, liver disorders or jaundice, a blood clot, diabetes, high blood pressure)</p>	<p>Do not supply Hana if the woman has:²</p> <ul style="list-style-type: none"> breast cancer or other known or suspected sex-steroid sensitive cancers (e.g. ovarian or uterine cancer) unresolved severe liver disorders (blood tests show liver function values have not returned to normal) active venous thrombosis or pulmonary embolism <p>Refer to doctor for assessment before supplying Hana if the woman has:^{2,3}</p> <ul style="list-style-type: none"> a history of breast, ovarian or uterine cancer current liver cancer or other liver disorders Type 1 or Type 2 diabetes <p>If none of these conditions apply, Hana is suitable.</p> <p>Hana is also suitable for women with a history of chloasma or thromboembolic disorders, or high blood pressure, but advise her:²</p> <ul style="list-style-type: none"> chloasma: can develop/recur, avoid sun or UV exposure whilst taking Hana thromboembolic disorders: can recur, visit doctor urgently if VTE symptoms are experienced (e.g. warm or swollen, painful leg; shortness of breath; or coughing up blood) high blood pressure: see doctor if sustained hypertension develops, or significant increase in blood pressure does not respond to antihypertensives
<p>Do you have any allergies?</p>	<p>If desogestrel or one of the excipients (refer to SmPC or Pharmacy guide for a full list), do not supply Hana and refer to doctor.²</p>
<p>Are you currently taking any regular medication or herbal remedies, or have you recently taken any other medication?</p>	<p>Ask woman for further information. Listen out for:^{2,3}</p> <ul style="list-style-type: none"> medications that may interact with Hana (e.g. some treatments for epilepsy, tuberculosis, pulmonary arterial hypertension, high blood pressure, fungal infection, bacterial infection, HIV/HCV, depression and emergency contraception), refer to SmPC or Pharmacy guide for a full list of medications intended treatment duration with medications <p>Consult PI of concomitant medications.²</p> <p>CYP enzyme-inducing medication: supply Hana but extra precautions required during and 28 days after medication use; other interacting medication: consult PI for recommendations.^{2,3}</p> <p>If interacting medications are used chronically or long-term, Hana may not be appropriate: refer to doctor for further advice.^{2,3}</p>

Starting Hana (max supply 3 months)

Ask whether woman is currently using hormonal contraception.

Women not currently using hormonal contraception	Women switching hormonal contraception
<p>No contraception use in the past month:²</p> <ul style="list-style-type: none"> start day 1 of bleeding, no extra precautions start days 2-5, extra precautions for 7 days <p><i>If period is already late or not when expected: take pregnancy test (≥3 weeks after last episode of unprotected sex) / visit doctor.²</i></p> <ul style="list-style-type: none"> <i>if negative, start Hana on day 1 of next period, no extra precautions, or days 2-5 with extra precautions for 7 days</i> <i>if positive, do not start Hana, visit doctor</i> <i>if period comes in the meantime, start Hana on day 1 of that period</i> <p>Following miscarriage or abortion:²</p> <ul style="list-style-type: none"> start immediately or within 5 days after miscarriage or abortion, no extra precautions <p>Following childbirth:²</p> <ul style="list-style-type: none"> start 1-21 days after childbirth if >21 days, extra precautions for 7 days <p><i>If woman had unprotected sex after 21 days post-childbirth, take pregnancy test (≥3 weeks after last episode of unprotected sex) / visit doctor.²</i></p>	<p>Confirm woman has used contraception correctly with no unscheduled breaks.</p> <p>Combined pill:²</p> <ul style="list-style-type: none"> start day after last active tablet, no extra precautions <p>Vaginal ring or skin patch:²</p> <ul style="list-style-type: none"> start day of removal, no extra precautions <p><i>If starting on the day after inactive tablet, ring-free or patch-free break, extra precautions for 7 days.²</i></p> <p>Mini-pill (progestogen-only pill):²</p> <ul style="list-style-type: none"> start day after last tablet, no extra precautions <p>Injection:²</p> <ul style="list-style-type: none"> start day next injection is due, no extra precautions <p>Implant or intrauterine system:²</p> <ul style="list-style-type: none"> start day of removal, no extra precautions

Women who have used emergency hormonal contraception since last period

Advise woman to wait until day 1 of next period to start Hana, extra precautions until this time.²

Remember, quick starting is outside the product label. If it is considered to be in the best interests of the woman, and she has used emergency contraception containing:²

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|---|--|
| <ul style="list-style-type: none"> levonorgestrel: Hana can be started on the same day, additional contraceptive measures (abstinence or barrier methods) for 7 days of Hana use | <ul style="list-style-type: none"> ulipristal acetate: wait 5 days before starting Hana, additional contraceptive measures (abstinence or barrier methods) during these 5 days and first 7 days of Hana use (i.e. 12 days in total) |
|---|--|

Encourage woman to advise doctor that she has been supplied with Hana in pharmacy.

Advise woman that if she experiences mood changes or depressive symptoms, including shortly after starting treatment, she should contact her doctor for medical advice as soon as possible. For further information on side effects and counselling advice refer to the Pharmacy Guide.

Refer to SmPC for additional information or clarification.

REPEAT SUPPLY OR CHANGING SUPPLY – WOMEN WHO ARE CURRENTLY USING OR HAVE RECENTLY USED DESOGESTREL

Age \geq 18: max supply 12 months, age $<$ 18: max supply 3 months

Check:

- 1 tablet has been taken at the same time every day, no break between packs and no missed doses
 - if not, chance of pregnancy: take pregnancy test \geq 3 weeks after last episode of unprotected sex, continue taking Hana until result available, **stop Hana** and visit doctor if positive²
- for any problems related to Hana or desogestrel use since initiation²
- for changes in health since last Hana purchase or desogestrel prescription²
- for changes in vaginal bleeding (e.g. bleeding between periods, or bleeding following sex)²
- for changes to regular medications or herbal remedies, or use of other medication²

If woman remains suitable for use: **supply Hana**, advise the woman that once current pack of Hana or prescription desogestrel finishes, start the new pack next day, without a break, regardless of bleeding.²

If the woman is under 18 years of age, **supply max 3 months of Hana**.

Women who have taken emergency hormonal contraception due to missed Hana tablet(s)

Emergency contraception containing:²

- levonorgestrel: Hana can be restarted on the same day, additional contraceptive measures (abstinence or barrier methods) for 7 days of Hana use
- ulipristal acetate: wait 5 days before restarting Hana, additional contraceptive measures (abstinence or barrier methods) during these 5 days and first 7 days of Hana use (i.e. 12 days in total)

Encourage woman to advise 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.

Advise woman that if she experiences mood changes or depressive symptoms, including shortly after starting treatment, she should contact her doctor for medical advice as soon as possible. For further information on side effects and counselling advice refer to the Pharmacy Guide.



HANA CHECKLIST

This short checklist will help to determine if Hana is the right oral contraceptive for you, and will help your pharmacist give you good advice. Please scratch off your answer to each of the questions and return this card to your pharmacist or medicines counter assistant when finished, who will use the revealed responses to guide your discussion.

How old are you?	Under 16
	16-18
	18+
Is there any possibility that you may be pregnant?	Yes
	No
	Unsure
Do you experience any bleeding between your periods or after sex?	Yes
	No
	Unsure
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)	Yes
	No
	Unsure
Do you have any allergies?	Yes
	No
	Unsure
Are you currently taking any regular medication or herbal remedies, or have you recently taken any other medication?	Yes
	No
	Unsure



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This short checklist will help to determine if Hana is the right oral contraceptive for you, and will help your pharmacist give you good advice. Please scratch off your answer to each of the questions and return this card to your pharmacist or medicines counter assistant when finished, who will use the revealed responses to guide your discussion.

How old are you?	Thank you, the pharmacist will need to ask you a few more questions
	Thank you
	Thank you
Is there any possibility that you may be pregnant?	Thank you, the pharmacist will advise you
	Thank you, the pharmacist may need to ask you a few more questions
	Thank you, the pharmacist will need to ask you a few more questions
Do you experience any bleeding between your periods or after sex?	Thank you, the pharmacist will need to discuss this with you
	Thank you
	Thank you, the pharmacist will need to discuss this with you
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)	Thank you, the pharmacist will need to ask you more questions
	Thank you
	Thank you, the pharmacist will need to ask you more questions
Do you have any allergies?	Thank you, the pharmacist will need to ask you more questions
	Thank you
	Thank you, the pharmacist will need to discuss this with you
Are you currently taking any regular medication or herbal remedies, or have you recently taken any other medication?	Thank you, the pharmacist will need to discuss this with you
	Thank you
	Thank you, the pharmacist will need to discuss this with you