

Desogestrel
film coated tablets
75 microgram

Hana

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film coated tablets
Desogestrel

Using Hana: summary of key points

- Hana is a contraceptive pill for women who want to prevent pregnancy.
- Take one tablet at the same time every day, without any break between packs.** Always read “When and how to take the tablets” before starting Hana.
- If you forget to take Hana,**
 - If you are **less than 12 hours late**, take the delayed pill straight away and take your further pills as usual. Hana will still protect you from pregnancy.
 - If you are **more than 12 hours late**, take the most recently missed pill straight away and leave any earlier missed pills in the strip. Take your further pills as usual. Use extra contraception (e.g. condoms) for the next 7 days. Missing tablets at any time in the cycle can reduce the efficacy of Hana and risk pregnancy but if you have missed one or more tablets in the first week of taking Hana and had sex in the week before missing the tablets, the risk you may get pregnant is higher. Ask your pharmacist for advice.

For full details, **see the chart in section 3**, under “If you forget to take Hana”.

- It is common for women taking Hana to have bleeding patterns which are different from their usual periods, or to have no periods at all (see section 4, “Changes to your periods”).
- In some circumstances it may not be appropriate to take Hana or it may be necessary to consult a doctor before taking Hana (see section 2.1 “Do not take Hana” and section 2.2 “Warnings and precautions”).
- Some medicines may reduce the efficacy of Hana. Tell your pharmacist if you are taking, or may start taking, any other medicines (see section 2.4 “Taking other medicines”).

Now read the rest of this leaflet. It includes other key points on the safe and effective use of this medicine that might be especially important for you.

This Leaflet was last revised in November 2020.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your pharmacist, doctor or family planning nurse. This includes any possible side effects not listed in section 4 of this leaflet.
- Talk to your doctor if you find Hana doesn't suit you, or you're finding it difficult to take as instructed.

What is in this leaflet

- What Hana is and what it is used for
- What you need to know before you take Hana
- How to take Hana
- Possible side effects
- How to store Hana
- Contents of the pack and other information

1 What Hana is and what it is used for

Hana is a daily contraceptive used to prevent pregnancy for women of childbearing age. It is an *oral hormonal contraceptive* (often called “the pill”). Hana works primarily by preventing a woman's egg cell from ripening (prevents ovulation); it also has effects on cervical mucus which makes it more difficult for sperm to enter the womb.

Hana contains a small amount of one type of female sex hormone: a *progestogen* called desogestrel. Unlike the *combined pill*, Hana does not contain any oestrogen hormone, in addition to the progestogen. For this reason, Hana is called a *progestogen-only pill* (POP).

Other methods of contraception are available with a prescription that might suit you better – see section 6.3 “More about contraception and women's health screening” at the end of this leaflet. Talk to your pharmacist, doctor or family planning nurse if you want more information.

In contrast to the combined pill, Hana can be used

- by women who **cannot take oestrogens**, or do not want to
- by women who are **breast-feeding**.

If you think you are post-menopausal, talk to your doctor. You may not need to take contraceptives.

Hormonal contraceptives, including Hana, do not protect you against HIV infection (AIDS) or any other sexually transmitted disease. Only condoms can protect you from sexually transmitted infections.

This product does not work as an emergency contraceptive. If it's taken every day it will protect against pregnancy in the future.

2 What you need to know before you take Hana

2.1 Do not take Hana

- if you have **cancer** that is affected by sex-steroid hormones, such as certain types of breast cancer, ovarian cancer, endometrial (uterine) cancer
- if you have a **blood clot** in the legs (*deep vein thrombosis*) or lungs (*pulmonary embolism*) (see section “Blood clots” in section 2.2 “Warnings and precautions”)
- if you have, or have had, **jaundice** (yellowing of the skin or whites of the eyes) or severe **liver diseases** and blood tests show your liver has not returned to normal
- if you have any **unexplained vaginal bleeding** between your periods, or if you repeatedly have bleeding after sex
- if you are **allergic** to desogestrel, or any of the other ingredients of Hana (listed in section 6, “Contents of the packs and other information”)
- if you are **pregnant** or think you may be pregnant. (Signs of pregnancy are listed in section 2.5 “Pregnancy and breast-feeding”).

Talk to your doctor or family planning nurse if any of these apply to you. Your doctor or family planning nurse may advise you to use a different method of birth control.

2.2 Warnings and precautions

Talk to your pharmacist, doctor or family planning nurse before taking Hana:

- if you have had **cancer** that is affected by progestogen hormones, such as certain types of breast cancer, ovarian cancer, endometrial (uterine) cancer
- if you have had a **blood clot** in the legs (*deep vein thrombosis*) or lungs (*pulmonary embolism*)
- if you have **liver cancer or other liver problems**
- if you have **high blood pressure**
- if you have **diabetes**
- if you have **epilepsy** (see section 2.4 “Taking other medicines”)
- if you have **tuberculosis** (see section 2.4 “Taking other medicines”)
- if you have had **chloasma** (yellowish-brown pigmentation patches on the skin, particularly of the face).

If any of these apply to you, you may still be able to take Hana but your doctor may want to see you from time to time.

It is common for women taking Hana to have bleeding patterns that are different from their usual periods. Some women will have bleeding less often, or none at all; some will have bleeding more often. Bleeding patterns may settle with time. A change in your bleeding pattern is not something you should normally be worried about if you are taking your pill as directed – see section 4.2 “Changes to your periods”.

Breast cancer

Breast cancer is rare in women under 40 years old. The risk increases as women get older. See your doctor as soon as possible if you feel any lumps or see a change in your breasts.

The risk of breast cancer is slightly higher in women taking any contraceptive pill, as compared to women of the same age not on the pill. The risk with progestogen-only pills, such as Hana, is thought to be similar to that in women on the combined pill. It may be lower, though more research is needed to be certain.

A woman's risk while on the combined pill is more affected by how old she is, rather than for how long she takes the pill. For example:

10,000 women take the combined pill for up to 5 years, and stop taking it by the age of 20 → 1 extra case of breast cancer found, on top of the 4 cases usually diagnosed in the 10 years afterwards

10,000 women take the combined pill for up to 5 years, and stop taking it by the age of 30 → 5 extra cases of breast cancer found, on top of the 44 cases usually diagnosed in the 10 years afterwards

10,000 women take the combined pill for up to 5 years, and stop taking it by the age of 40 → 20 extra cases of breast cancer found, on top of the 160 cases usually diagnosed in the 10 years afterwards

Compared to the risk of getting breast cancer ever in life, the increased risk associated with the combined pill is low. It may be that women on the combined pill were examined more often, so that the breast cancer was noticed earlier.

When women stop taking the pill, their risk of breast cancer gradually reduces so that, within 10 years of stopping, their risk is the same as for those who have never taken it.

Blood clots

Blood clots in major arteries and veins are rare but can cause serious health problems. The risk of a blood clot is higher in women on any type of contraceptive pill (but no higher than the risk in pregnant women). The risk with progestogen-only pills, such as Hana, is thought to be lower than in women on the combined pill, but this has yet to be confirmed.

A clot in the deep veins of the leg (called a *deep vein thrombosis*, or DVT) can cause the following symptoms, usually in the calf:

- swelling of the leg
- redness and warm skin
- severe pain in the leg

A clot in the leg can travel to the lungs and stop there (*pulmonary embolism*), which can be fatal.

Signs of a blood clot in the lungs include:

- chest pain
- breathlessness
- coughing up blood

Contact your doctor immediately if you notice any of the signs above. Do not take Hana if you have a blood clot.

Being immobile can increase your risk of a blood clot. Consult your doctor at least four weeks before planned surgery to see whether you should stop using Hana during that time.

Pregnancy outside the womb (ectopic pregnancy)

Hana consistently inhibits ovulation (see section 1 “What Hana is and what it is used for”) and so reduces the risk of pregnancy outside the womb. However, contact your doctor immediately if you have sudden or severe pain in the lower abdomen or stomach area with or without vaginal bleeding, even if you don't think you are pregnant.

Mental health

Some women using hormonal contraceptives, including Hana, have reported depression or depressed mood. Depression can be serious and sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms, **contact your doctor as soon as possible**.

High blood pressure (hypertension)

If you develop high blood pressure during the use of Hana, or if your blood pressure remains high despite treatment you have been given, contact your doctor to decide whether Hana should be stopped.

Effect on bone mineral density

Because Hana prevents ovulation, it reduces the overall level of estrogen hormone in the bloodstream. It is not known whether this reduction has any effect on bone density and risk of fracture in later life.

2.3 Children and adolescents

No clinical data on efficacy and safety are available in adolescents below 18 years.

2.4 Taking other medicines

Tell your pharmacist, doctor or family planning nurse if you are taking any other medicines, have recently taken any, or might in the future. This includes medicines that you buy without a prescription, and herbal remedies.

If any pharmacist, doctor or family planning nurse prescribes you another medicine, tell them that you take Hana. They can tell you if the other medicine is OK to take at the same time, and whether you need to use extra contraception (for example, condoms).

If you are using these medicines or herbal remedies listed below either **chronically** or for **long-term treatment**, you should **consult your doctor** as an alternative method of contraception may be more appropriate for you.

Substances which may lead to unexpected bleeding and/or contraceptive failure in women using Hana

These include treatments for:

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

All these medicines or herbal remedies can stop Hana working properly.

If you are using any of these medicines or herbal remedies for **short-term** treatment, you can continue taking Hana, but **you must also use extra contraception** (for example, condoms) every time you have sex during treatment and until 28 days after stopping the last dose of the other medicine or herbal remedy.

If you are using any of these medicines or herbal remedies either **chronically** or for a **long-term** treatment, you should **consult your doctor** for further advice.

Substances increasing the blood levels of Hana

These include medicines used for the treatments of:

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

The leaflet for these medicines needs to be consulted to identify potential interactions and any recommendations. **Ask your pharmacist for advice.**

Substances with variable effects on the blood levels of Hana

These include treatments for:

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

The leaflet for these medicines needs to be consulted to identify potential interactions and any recommendations. **Ask your pharmacist for advice. In case of doubt, you must use extra contraception (for example, condoms) during treatment with these medicines.**

Hana may also interfere with how other medicines work, causing them to either have an increased effect (e.g. medicines containing ciclosporin) or a decreased effect (e.g. lamotrigine).

For more advice, ask your pharmacist.

Taking emergency contraceptive containing ulipristal acetate

Using Hana and emergency contraception containing ulipristal acetate together can alter the effect of both these medicines, resulting in reduced contraceptive effect and increased risk of pregnancy.

If you have used emergency contraception containing ulipristal acetate during your cycle, you must wait 5 days after taking ulipristal acetate before taking Hana. **You must also use additional contraception** (for example, condoms) every time you have sex during the 5 days while you wait to start or resume taking Hana and for the first 7 days of taking Hana (ie. for a **total of 12 days**).

For more advice, ask your pharmacist, doctor or family planning nurse.

2.5 Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant

Do not use Hana if you are pregnant, or think you may be pregnant. Take a pregnancy test or talk to your pharmacist, doctor or family planning nurse if your period is late after missing any pills in the last month, or if you think you may be pregnant. If you become pregnant, **stop taking Hana and see your doctor**.

Signs that you may be pregnant include: a missed period, tender breasts, feeling sick, tiredness, and mood swings.

If you are breast-feeding

Hana may be used while you are breast-feeding. Desogestrel, the active substance of Hana, does not appear to influence the production or the quality of breast-milk. However, there have been infrequent reports of a decrease in breast milk production while using desogestrel. A small amount of desogestrel passes into the milk.

Researchers have followed children who were breast-fed for 7 months while their mothers were using desogestrel. The children's health was studied up until they were 2½ years old. No effects on their growth or development were seen.

