



PACKAGE LEAFLET: INFORMATION FOR THE USER

Moonia 75 micrograms film-coated tablets
Desogestrel

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It is not suitable for all women, so you should not give it to anyone else as it may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Moonia is and what it is used for
2. What you need to know before you take Moonia
3. How to take Moonia
4. Possible side effects
5. How to store Moonia
6. Contents of the pack and other information

1. WHAT MOONIA IS AND WHAT IT IS USED FOR

Moonia is used to prevent pregnancy.

Moonia contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason Moonia is called a progestogen-only-pill (POP).

Contrary to the combined pill, the POP does not contain an oestrogen hormone next to the progestogen.

Most POPs work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the primary action of combined pills. Moonia is distinct from POPs in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, Moonia provides high contraceptive efficacy. In contrast to the combined pill, Moonia can be used by women who do not tolerate oestrogens and by women who are breastfeeding.

A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Moonia. You also may not have any bleeding at all.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MOONIA

Moonia, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take Moonia

- If you are allergic to desogestrel or to any of the other ingredients of this medicine (listed in section 6).
- If you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel (e.g. of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)).
- If you have or have had jaundice (yellowing of the skin) or severe liver disease and your liver function is still not normal.
- If you have or are suspected to have a cancer that is sensitive to sex-steroids, such as certain types of breast cancer.
- If you have any unexplained vaginal bleeding.
- If you are allergic to peanut or soya.

Tell you doctor before you start to use Moonia if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of birth control.

Consult your doctor immediately if any of these conditions appear for the first time while using Moonia.

Warnings and precautions

Talk to your doctor or pharmacist before you start to use Moonia, if

- you have ever had cancer of the breast.
- you have liver cancer, since a possible effect of Moonia cannot be excluded.
- you have ever had a thrombosis.
- you have diabetes.
- you suffer from epilepsy (see section 'Other medicines and Moonia').
- you suffer from tuberculosis (see section 'Other medicines and Moonia').
- you have high blood pressure.
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so avoid too much exposure to the sun or ultraviolet radiation.

When Moonia is used in the presence of any of these conditions, you may need to be kept under close observation. Your doctor can explain what to do.

Moonia and breast cancer

Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts. Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the Pill. Breast cancer is rare under 40 years of age but the risk increases as

the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if the age until which the woman continues to take the Pill is higher. How long she takes the Pill is less important.

In every 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group. Likewise, in 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed. In 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.

The risk of breast cancer in users of progestogen-only pills like Moonia is believed to be similar to that in women who use the Pill, but the evidence is less conclusive.

Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill. It is not known whether the difference in breast cancer risk is caused by the Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

Moonia and thrombosis

See your doctor immediately; if you notice possible signs of a thrombosis (see also 'Regular Check-ups') Thrombosis is the formation of a blood clot which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". As a result, fatal situations may occur. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant. The risk is higher in Pill-users than in non-users. The risk with progestogen-only pills, like Moonia, is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

Children and adolescents

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

Other medicines and Moonia

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may stop Moonia from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and Phenobarbital) or tuberculosis (e.g. rifampicin), HIV infections (e.g. ritonavir) or other infectious diseases (e.g. griseofulvin), stomach upset (medical charcoal), depressive moods (the herbal remedy St John's wort).

Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

Moonia may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

Pregnancy and breast-feeding

Pregnancy

Do not use Moonia if you are pregnant, or think you may be pregnant.

Breast-feeding

Moonia may be used while you are breast-feeding. Moonia does not influence the production or the quality of breast milk. However, a small amount of the active substance of Moonia passes over into the milk.

The health of children breast-fed for 7 months whose mothers were using Moonia has been studied up to 2.5 years of age. No effects on the growth and development of the children were observed.

If you are breast-feeding and want to use Moonia, please contact your doctor.

Driving and using machines

There are no indications of any effect of the use of Moonia on alertness and concentration.

Moonia contains lactose (milk sugar) and soy bean oil.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

If you are allergic to peanut or soya, do not use this medicinal product.

Regular check-ups

While you are using Moonia your doctor will tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible if:

- you have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis).
- you have a sudden, severe stomach ache or look jaundiced (possibly indicating liver problems);
- you feel a lump in your breast (possibly indicating breast cancer);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are pregnant.

3. HOW TO TAKE MOONIA

Route of administration

Moonia is for oral use.

When and how you should take Moonia

The Moonia pack contains 28 tablets. The days of the week are printed in the blister and also arrows are printed indicating the order to take the pills. Each day correspond with one tablet. Every time you start a new pack of Moonia, take a tablet from the top row. Don't start with just any tablet. For example if you start on a Wednesday, you must take the tablet from the top row marked with 'WED' (Wednesday). Continue to take one tablet a day until the pack is empty, always following the direction indicated by the arrows. By looking at the pill pack you can easily check if you have already taken a tablet on a particular day. Take your tablet each day at about the same time.

Swallow the tablet whole, with water. You may have some bleeding during the use of Moonia, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of Moonia on the next day – thus without interruption and without waiting for a bleed.

When to start with the first strip Moonia

When no hormonal contraceptive has been used in the past month

Wait for your period to begin. On the first day of your period take the first Moonia tablet.

You need not take extra contraceptive precautions.

You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

When you change from a combined pill, vaginal ring, or transdermal patch

You can start taking Moonia on the day after you take the last tablet from the present Pill pack, or on the last day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free break). If your present Pill pack also contains inactive tablets you can start Moonia on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, you need not take extra contraceptive precautions.

You can also start at the latest the day following the tablet-, ring-, patch-free break, or placebo tablet interval, of your present contraceptive. If you follow these instructions, make sure you use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

When changing from another progestogen-only pill

You may stop taking it any day and start taking Moonia right away. You need not take extra contraceptive precautions.

When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD)

Start using Moonia when your next injection is due or on the day that your implant or your IUD is removed. You need not take extra contraceptive precautions.

After having a baby

You can start Moonia between 21 and 28 days after the birth of your baby. If you start later, make sure you use an additional contraceptive method (barrier method) until you have completed the first 7 days of tablet-taking.

However, if intercourse has already occurred, pregnancy should be excluded before starting Moonia use. Additional information for breast-feeding women can be found in 'Pregnancy and Breast-feeding' in section 2. Your doctor can also advise you.

After a miscarriage or a premature termination of pregnancy

Your doctor will advise you.

If you forget to take Moonia

If you are **less than 12 hours** late in taking a tablet, the reliability of Moonia is maintained. Take the missed tablet as soon as you remember and take the next tablets at the usual times.

If you are **more than 12 hours** late in taking any tablet, the reliability of Moonia may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. Take the last missed tablet as soon as you remember and take the next tablets at the usual times. Use an additional contraceptive method (barrier method) too for the next 7 days of tablet-taking. If you missed one or more tablets in the first week of tablet-intake and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

If you suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea)

Follow the advice for missed tablets in the section above. If you vomit or use medical charcoal within 3 - 4 hours after taking your Moonia tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed.

If you take more Moonia than you should

There are no mentions of seriously damaging results of taking too many Moonia pills simultaneously. Should you have taken a number of pills simultaneously, you may suffer from nausea, vomiting or vaginal blood loss. If you find out that a child has taken multiple pills, contact immediately your doctor for advice.

If you stop taking Moonia

You can stop taking Moonia whenever you want. From the day you stop you are no longer protected against pregnancy.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious undesirable effects associated with the use of Moonia are described in the sections "Moonia and breast cancer" and "Moonia and thrombosis" in section 2 "What you need to know before you take Moonia" Please read this section for additional information and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals during the use of Moonia. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Moonia is decreased. In general, you need not take any action; just continue to take Moonia. If, however, bleeding is heavy or prolonged you should consult your doctor.

Following side effects have been reported:

- **Common** (*may affect up to 1 in 10 women*): mood changes, depressed mood, decreased sexual drive (libido), headache, nausea, acne, breast pain, irregular or no menstruation, increased body weight.
- **Uncommon** (*may affect up to 1 in 100 woman*): infection of the vagina, difficulties in wearing contact lenses, vomiting, hair loss, painful menstruation, ovarian cyst, tiredness.
- **Rare** (*may affect up to 1 in 1,000 woman*): Skin conditions such as: rash, hives, painful blue-red skin lumps (erythema nodosum).

Apart from these side effects, breast secretion may occur.

You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx; difficulty swallowing; or hives and difficulty breathing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MOONIA

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use Moonia after the expiry date which is stated on the carton after "Do not use after:" or "EXP." The Expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Moonia contains

The active substance is: desogestrel (75 micrograms)

The other ingredients are: lactose monohydrate, maize starch, povidone K30, RRR- α -tocopherol, soybean oil, silica, colloidal anhydrous, silica, colloidal hydrated, stearic acid, hypromellose, polyethylene glycol, titanium dioxide (E 171) (see also "Moonia contains lactose (milk sugar) and soy bean oil" in section 2).

What Moonia looks like and content of the pack

One blister pack of Moonia contains 28 white round film-coated tablets (with a diameter of about 5 mm). Each carton contains 1, 3 or 6 blisters.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

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