Package Leaflet: Information for the patient

# **Desogestrel 75microgram Film-coated Tablets**

Read this entire leaflet carefully before you start taking the medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. It is not suitable for all women, so you should not give it to anyone else as it may
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

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Desogestrel is used to prevent pregnancy. Desogestrel contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason Desogestrel is called a progestogen-only-pill (POP), or a mini-pill. Contrary to the combined pill, the POP or mini-pill does not contain an oestrogen hormone next to the progestogen.

Most POPs or minipills 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. Desogestrel is distinct from other mini-pills in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, Desogestrel provides high contraceptive efficacy. In contrast to the combined pill, Desogestrel can be used by women who do not tolerate destrogens and by women who are breastfeeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Desogestrel. You also may not have any bleeding at all.

## **2** Before you take Desogestrel

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

## Do not take Desogestrel

- If you are allergic to any of the ingredients of Desogestrel.
- 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
- **progestogens**, 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 Desogestrel if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of

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

## Take special care with Desogestrel

- Tell your doctor before you start to use Desogestrel, if
- you have ever had cancer of the breast.
- you have liver cancer, since a possible effect of Desogestrel cannot be excluded.
- you have ever had a thrombosis.
- you have diabetes
- you suffer from epilepsy (see section 'Taking other medicines'). you suffer from **tuberculosis** (see section 'Taking other medicines').
- 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

When Desogestrel 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.

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 progestogen-only pills like Desogestrel is believed to be similar to that in women who use the Pill, but the evidence is

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

#### Desogestrel 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 Desogestrel, is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

## Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, including medicines obtained without a prescription. Some medicines may stop Desogestrel 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.

Desogestrel 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 Desogestrel if you are pregnant, or think you may be pregnant.

Desogestrel may be used while you are breast-feeding. Desogestrel 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. Aa small amount of the active substance of Desogestrel

passes over into the milk. The health of children breast-fed for 7 months whose mothers were using Desogestrel 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 Desogestrel, please contact your doctor.

Driving and using machines

There are no indications of any effect of the use of Desogestrel on alertness

Important information about some of the ingredients of Desogestrel Desogestrel 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.

**BACK SIDE** / PLEASE, INCLUDE YOUR DESIGN ON THIS KEYLINE

### Use in children and adolescents

No clinical data on effectiveness and safety are available in children and adolescents below 18 years

#### Regular check-ups

While you are using Desogestrel you should see your doctor regularly at least twice a year.

#### Contact your doctor as soon as possible if:

- you have severe pain or swelling in either of your legs, unexplained pains i 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
- 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 Desogestrel

When and how you should take Desogestrel The Desogestrel 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 Desogestrel , 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 Desogestrel, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of Desogestrel on the next day – thus without interruption and without waiting for a bleed.

## When to start with the first strip Desogestrel

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

Desogestrel 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 Desogestrel 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 Desogestrel 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 (mini-pill)

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

intrauterine device (IUD) Start using Desogestrel when your next injection is due or on the day that your

When changing from an injectable or implant or a progestogen-releasing

implant or your IUD is removed. You need not take extra contraceptive precautions. After having a baby

You can start Desogestrel between 21 and 28 days after the birth of your baby. If you start later, make sure you use during the first cycle an additional contraceptive method (barrier method) for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before starting Desogestrel use. Additional information for breast-feeding women can be found in 'Pregnancy and Breast-feeding' in section 2. Your

After a miscarriage or a premature termination of pregnancy

### Your doctor will advise you. If you forget to take Desogestrel

doctor can also advise you.

If you are less than 12 hours late in taking a tablet, the reliability of Desogestrel 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 Desogestrel may be reduced. The more consecutive tablets you have missed,

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

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

### If you take more Desogestrel than you should

There are no mentions of seriously damaging results of taking too many Desogestrel 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 your doctor for advice.

### If you stop taking Desogestrel

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

### 4 Possible side effects

Like all medicines, Desogestrel can cause side effects, although not everybody gets them. Serious undesirable affects associated with the use of Desogestrel are described the paragraphs "Breast Cancer" and "Thrombosis" in section 2 "Before you take Desogestrel" 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 Desogestrel. 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 Desogestrel is decreased. In general, you need not take any action; just continue to take Desogestrel. If, however, bleeding is heavy or prolonged consult your doctor.

- Common side effects (affects 1 to 10 users in 100) are: mood altered, decreased sexual drive (libido), headache, nausea, acne, breast pain,
- irregular or no menstruation, increased body weight. • Uncommon side effects (affects 1 to 10 users in 1,000) are: infection of the vagina, difficulties in wearing contact lenses, vomiting, hair loss, painful menstruation, ovarian cyst, tiredness.
- Rare side effects (affects 1 to 10 users in 10,000) are: rash, hives, painful blue-red skin lumps (erythema nodosum). These are skin conditions.

Apart from these side effects, breast secretion may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5 How to store Desogestrel

## Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions. Do not use Desogestrel 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6 Further information

## What Desogestrel contains

The active substance is: desogestrel (75 microgram)

The other ingredients are: lactose monohydrate, maize starch, povidone K30, all-rac-α-tocopherol, soybean oil, silica, colloidal anhydrous, silica, colloidal hydrated, stearic acid, hypromellose, polyethylene glycol, titanium dioxide (E 171) (see also "Important information about some of the ingredients of Desogestrel in section 2).

What Desogestrel looks like and content of the pack One blister pack of Desogestrel contains 28 white round film-coated tablets.

Each carton contains 1, 3 or 6 blisters.

Not all pack sizes may be available.

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This leaflet was last approved on May 2021