

PATIENT INFORMATION SHEET: INFORMATION FOR THE USER

Desogestrel

75 microgram Film-coated Tablets

Read all of this leaflet carefully before you start taking this 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 may harm them even if their signs of illness are the same as yours. If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT DESOGESTREL IS AND WHAT IT IS USED FOR

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 oestrogens and by women who are breast-feeding. 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. WHAT YOU NEED TO KNOW 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 desogestrel, or any of the ingredients of Desogestrel Tablets.
- 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 grows under the influence of 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 your doctor before you start to take Desogestrel 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 Desogestrel.

Warnings and precautions

- Tell your doctor before you start to take 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 ‘Other medicines and Desogestrel’).
 - you suffer from tuberculosis (see section ‘Other medicines and Desogestrel’).
 - 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 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.

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 Desogestrel 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.

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).

Psychiatric disorders:

Some women using hormonal contraceptives including Desogestrel have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Use in adolescents

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

Other medicines and Desogestrel

Tell your doctor, pharmacist or Family Planning Nurse if you are taking, have recently taken or might take any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take Desogestrel. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long or whether the use of another medicine you need must be changed. Some medicines:

- can have an influence on the blood levels of Desogestrel.
- can make it less effective in preventing pregnancy.
- can cause unexpected bleeding.

These include medicines used for the treatment of

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate and Phenobarbital);
- tuberculosis (e.g. rifampicin, rifabutin);
- HIV infections (e.g. ritonavir, efavirenz);
- Hepatitis C virus infection (e.g. boceprevir, telaprevir);
- or other infectious diseases (e.g. griseofulvin);
- high blood pressure in the blood vessels of the lungs (bosentan);
- depressive moods (the herbal remedy St John’s wort);
- certain bacterial infections (e.g. clarithromycin, erythromycin);
- fungal infections (e.g. ketoconazole, itraconazole, fluconazole);
- high blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem).

If you are taking medicines or herbal products that might make Desogestrel less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Desogestrel may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. 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 (e.g. lamotrigine).

Pregnancy and breast-feeding

Pregnancy
Do not use Desogestrel if you are pregnant, or think you may be pregnant. Breast-feeding

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. A small amount of the active substance of Desogestrel Tablets passes over into the milk.

The health of children who were breast-fed for 7 months while their 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 and concentration.

Important information about some of the ingredients of Desogestrel Tablets

Desogestrel Tablets contain lactose (milk sugar) and soybean oil. Please, contact your doctor before taking Desogestrel if you have been told by your doctor you are intolerant to some sugars. If you are allergic to peanut or soya, do not use this medicinal product.

