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PACKAGE LEAFLET: INFORMATION FOR THE USER

Desorex 75 micrograms film-coated tablets

Desogestrel



Pharmacode

Somex Pharma

Read all of this leaflet carefully before you start using this 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

- 1. What Desorex is and what it is used for
2. Before you take Desorex
3. How to take Desorex
4. Possible side effects
5. How to store Desorex
6. Further information

1. WHAT DESOREX IS AND WHAT IT IS USED FOR

Desorex is used to prevent pregnancy in women over 18 years. It contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason Desorex is called a progestogen-only pill (POP), or a mini-pill. Unlike the combined pill, the POP or mini-pill does not contain an oestrogen hormone, only a progestogen.

Most POPs or mini-pill work primarily by preventing the sperm cells from entering the womb. They do not always prevent the egg cell from ripening, which is the primary action of combined pills. Desorex 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, Desorex provides high contraceptive efficacy.

In contrast to the combined pill, Desorex 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 Desorex. You may not have any bleeding at all.

2. BEFORE YOU TAKE DESOREX

Do not take this medicine

- if you are allergic to desogestrel or any of the other ingredients of Desorex.
- If any of these conditions appears for the first time while using Desorex you should consult your doctor promptly.
- if you are pregnant or think you might be pregnant.
- 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) that can among others migrate into the lungs and cause a pulmonary embolism).
- if you 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.

Tell your doctor before you start to use this medicine 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 this medicine.

Take special care with Desorex

- if you have ever had breast cancer.
- if you have liver cancer, since a possible effect of Desorex on liver cancer cannot be excluded.
- if you have reduced liver function.
- if you have ever had a thrombosis.
- if you have diabetes.
- if you suffer from epilepsy (see section 2 "Taking other medicines").
- if you suffer from tuberculosis (see section 2 "Taking other medicines").
- if you have high blood pressure or your blood pressure increases significantly.
- if 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.

Please tell your doctor if one of these conditions applies to you.

When Desorex 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.

Regular Check-ups

When you are using this medicine, 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 pain in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis or an embolism respectively);
- if you have a sudden, severe stomach ache or look jaundiced (possibly indicating liver problems);
- if you feel a lump in your breast (possibly indicating a breast cancer);
- if 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);
- if you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- if you have unusual, heavy vaginal bleeding;
- if you suspect that you are pregnant.

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.

Increase of the risk of getting breast cancer when taking Desorex.

The information is calculated on 10,000 women:

Table with 3 columns: Discontinuation of the intake of the Pill at the age of, Cases of breast cancer without taking the Pill, Cases of breast cancer in women who take the Pill (max. 5 years long). Rows for 20, 30, and 40 years.

The risk of breast cancer in users of progestogen-only pills like this medicine is believed to be similar to that in women who use pills that also contain oestrogens (combined pills), 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 section 2 "Do not take this medicine..."). 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. This causes 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 difference in the risk of getting a thrombosis with progestogen-only pills like Desorex compared to Pills that also contain oestrogens (combined Pills) is unknown.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may stop your tablets from working properly and may lead to breakthrough bleeding or contraceptive failure. These include medicines used for the treatment of

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and phenobarbital),
- tuberculosis (e.g. rifampicin, rifabutin),
- HIV infections (e.g. ritonavir, nelfinavir),
- or other infectious diseases (e.g. griseofulvin), stomach upset (medical charcoal), depressive moods (the herbal remedy St. Jones wort),
- in cases of transplantations (e.g. ciclosporin).

If you take one of the listed medicines together with Desorex you need to take additional contraceptive precautions during the time of concomitant drug administration and for 28 days after their discontinuation. It may also affect the mode of action of certain medicines in the body, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

Taking Desorex with food and drink

You can take this medicine with or without food and drink.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Do not use Desorex if you are pregnant, or think you might be pregnant.

Breast-feeding

Desorex may be used while you are breast-feeding. Desorex 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 desorex. A small amount of the active substance of desorex passes over into the milk. If you are breast feeding and want to use this medicine, please contact your doctor.

Driving and using machines

Desorex has no influence on your ability to drive or using machines.

Important information about some of the ingredients of Desorex

This medicine contains lactose (milk sugar). If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicinal product.

GRAIN DIRECTION

600 mm

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10 mm
Print Free Zone

10 mm
Print Free Zone

10 mm

Size -148X600 mm 50-60 GSM paper

■ Non printing colour

22 mm

148 mm

190 mm

GRAIN DIRECTION

600 mm

10 mm
10 mm
Print Free
Zone

10 mm
Print Free
Zone

10 mm

Use in adolescents

There is no data to support the use of Desorex in adolescent girls under 18 years.

3. HOW TO TAKE DESOREX

Always take your tablets exactly as your doctor has told you respectively as described in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Method of administration

- each blister of Desorex contains **28 tablets**.
- the first tablet should be taken **on the first day of your menstrual bleeding**.
- take **one tablet daily**.
- **Swallow the tablet whole** with a sufficient amount of water.

Arrows are printed on the front side of the pack between the tablets. If you turn over your pack and look at the back side, you will see the days of the week printed on the foil. Each day corresponds with one tablet. Every time you start a new pack of your medicine, take a tablet from 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 (at the back) with "WED". Continue to take one tablet a day, until the pack is empty. **Always follow the direction indicated by the arrows.** By looking at the back of your pack you can easily check if you have already taken your tablet on a particular day.

Pharmacoed

Take your tablet each day at about the same time so that the **interval between two tablets is always 24 hours**. You may have some bleeding during the use of Desorex, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of your tablets on the next day - thus without interruption and without waiting for a bleed.

Starting your first pack of Desorex

- **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 Desorex 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 changing from a combined pill, vaginal ring, or transdermal patch**
You can start taking Desorex on the day after you take the last tablet from the present Pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free interval). If your present Pill pack also contains inactive tablets you can start Desorex 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 on the day following the tablet-, ring-, patch-free interval, or after the intake of the inactive tablets 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 progesteron-only containing pill (mini pill) to Desorex**
You may stop taking it any day and start taking this medicine right away. You need not take extra contraceptive precautions.
- **When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD) to Desorex**
Start using this medicine 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**
After delivery you can start taking Desorex before your menstrual bleeding returns.
If you start later than 21 days after delivery, 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 must be excluded before starting Desorex use.
- **After a miscarriage or an abortion**
Your doctor will advise you.

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

If you take more Desorex than you should

There have been no reports of serious harmful effects from taking too many desogestrel-containing tablets at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For more information ask your doctor for advice.

If you forget to take Desorex

If you are **less than 12 hours late** in taking a tablet, the reliability of this medicine is maintained. Take the missed tablet as soon as you remember and take the next tablet at the usual time. If you are **more than 12 hours late** in taking any tablet, the reliability of Desorex 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. This means that you possibly take 2 tablets on one day. Use an **additional contraceptive method (such as condoms)** 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)

If you **vomit** or have **severe diarrhoea** or if you use **medical charcoal** within 3-4 hours after taking your Desorex tablet, the active ingredient may not have been completely absorbed and the reliability of Desorex may be reduced. In such a case you need **additional contraceptive methods (such as condoms)** for the next 7 days. Take the next tablet at the usual time.

If you stop taking Desorex

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Serious undesirable effects associated with the use of Desorex are described in the paragraphs "Breast cancer" and "Thrombosis" in section 2 "Before you take Desorex". 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 Desorex. 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 Desorex is decreased. In general, you need not take any action. Just continue to take Desorex. If, however, bleeding is heavy or prolonged you should consult your doctor.

The side effects rating was based on the following frequency data:

Very common:	more than 1 user in 10
Common:	1 to 10 users in 100
Uncommon:	1 to 10 users in 1,000
Rare:	1 to 10 users in 10,000
Very rare:	less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

Users of desogestrel have reported the following side effects:

- Common**
- Mood altered, decreased sexual drive (libido)
 - Headache
 - Nausea
 - Acne
 - Breast pain, irregular or no menstruation
 - Increased body weight
- Uncommon**
- Infection of the vagina
 - Difficulties in wearing contact lenses
 - Vomiting
 - Hair loss
 - Painful menstruation, ovarian cyst
 - Tiredness
- Rare**
- Rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin conditions)

Apart from these side effects, breast secretion may occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DESOREX

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Desorex does not require any special storage conditions.

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 Desorex contains

- The active substance is: desogestrel (75 microgram).

The other ingredients are: lactose monohydrate (see also "Important information about some of the ingredients of Desorex" in section 2), maize starch, povidone PVP K-30, stearic acid, all-rac-alpha-tocopherol, silica, colloidal anhydrous, Tabcoat TC-white (Hydroxypropyl Methyl Cellulose, Polyethylene Glycol, Talc, TitaniumDioxide).

What Desorex looks like and contents of the pack

Desorex tablets are white to off white, circular, biconvex film-coated tablets without embossing.

One blister pack of Desorex contains 28 film-coated tablets. Each carton contains 1, 3 or 6 blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Strandhaven Ltd T/A Somex Pharma, Ilford, Essex IG3 8BS

Manufacturer
Strandhaven Ltd T/A Somex Pharma, Ilford, Essex IG3 8RA

This medicinal product is authorised in the Member States of the EEA under the following names:
Desorex 75micrograms film-coated tablets

This leaflet was last approved in 07/2020