

# Desogestrel Rowex 75 microgram Film-coated tablets



desogestrel

**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 any further questions, ask your doctor or 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 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 Rowex is and what it is used for
  2. What you need to know before you take Desogestrel Rowex
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  4. Possible side effects
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## 1. What Desogestrel Rowex is and what it is used for

Desogestrel Rowex is used to prevent pregnancy. Desogestrel Rowex contains a small amount of one type of female sex hormone, the progestogen **desogestrel**. For this reason Desogestrel Rowex 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. Desogestrel Rowex is distinct from most POPs in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, Desogestrel Rowex provides high contraceptive efficacy.

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

## 2. What you need to know before you take Desogestrel Rowex

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

- if you are allergic to desogestrel, or 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 your doctor before you start to use Desogestrel Rowex 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 Rowex.

### Warnings and precautions

Talk to your doctor before you start to use Desogestrel Rowex, if

- you have ever had **breast cancer**.
- you have **liver cancer**, since a possible effect of Desogestrel Rowex cannot be excluded.
- you have ever had a **thrombosis**.
- you have **diabetes**.
- you suffer from **epilepsy** (see section ‘Other medicines and Desogestrel Rowex’).
- you suffer from **tuberculosis** (see section ‘Other medicines and Desogestrel Rowex’).
- 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 Rowex 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 Rowex 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 Rowex, 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 Desogestrel Rowex**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may stop Desogestrel Rowex from working properly. These include medicines used for the treatment of

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and phenobarbital)
- 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 Rowex 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 Rowex if you are pregnant, or think you may be pregnant.

**Breast-feeding**

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

The health of children breast-fed for 7 months whose mothers were using Desogestrel Rowex 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 Rowex, please contact your doctor.

**Driving and using machines**

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

**Desogestrel Rowex contains lactose (milk sugar) and soy bean oil.**

Please contact your doctor before taking Desogestrel Rowex if you have been told by your doctor that you are intolerant to some sugars.

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

**Regular Check-ups**

When you are using Desogestrel Rowex, 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 a sign of 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 Desogestrel Rowex

**When and how to take the tablets?**

The Desogestrel Rowex pack contains 28 tablets. The days of the week are printed on the blister foil. Arrows are printed on both sides for clear directions and indicate the order in which to take the tablets. Each day corresponds to one tablet.

Every time you start a new pack of Desogestrel Rowex, 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 (at the back) with WED. Continue to take one tablet a day until the pack is empty, always following 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.

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

Starting your first pack of Desogestrel Rowex

- 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 Rowex 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 Desogestrel Rowex 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 break). If your present Pill pack also contains inactive tablets you can start Desogestrel Rowex 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 Desogestrel Rowex 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 Desogestrel Rowex 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 Desogestrel Rowex between 21 to 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 Desogestrel Rowex 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 an abortion:**  
Your doctor will advise you.

If you forget to take Desogestrel Rowex

- If you are **less than 12 hours** late in taking a tablet, the reliability of Desogestrel Rowex 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 Rowex 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 Desogestrel Rowex tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed.

If you take more Desogestrel Rowex than you should

There have been no reports of serious harmful effects from taking too many Desogestrel Rowex 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 stop taking Desogestrel Rowex

You can stop taking Desogestrel Rowex 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, this medicine can cause side effects, although not everybody gets them.

Serious undesirable effects associated with the use of Desogestrel Rowex are described in the paragraphs “Breast cancer” and “Thrombosis” in section 2 “What you need to know before you take Desogestrel Rowex.” 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 Rowex. 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 Rowex is decreased. In general, you need not take any action; just continue to take Desogestrel Rowex. If, however, bleeding is heavy or prolonged you should consult your doctor.

Users of Desogestrel Rowex have reported the following side effects:

Common (occurring in more than one per 100 users) are:	Uncommon (occurring in more than one per 1000 users but not more than one per 100 users) are:	Rare (occurring in less than one per 1000 users) is:
<ul style="list-style-type: none"><li>mood altered, depressed mood, decreased sexual drive (libido)</li><li>headache</li><li>nausea</li><li>acne</li><li>breast pain, irregular or no menstruation</li><li>increased body weight</li></ul>	<ul style="list-style-type: none"><li>infection of the vagina</li><li>difficulties in wearing contact lenses</li><li>vomiting</li><li>hair loss</li><li>painful menstruation, ovarian cyst</li><li>tiredness</li></ul>	<ul style="list-style-type: none"><li>rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin conditions)</li></ul>

Apart from these side effects, breast secretion may occur.

You should see your doctor immediately if you experience symptoms of angioedema, such as (i) swollen face, tongue or pharynx; (ii) difficulty to swallow; or (iii) hives and difficulties to breathe.

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 HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Desogestrel Rowex

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

Do not store above 30°C. Store in the original package in order to protect from light.

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

Do not use this medicine if you notice visible signs of deterioration.

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 Desogestrel Rowex contains

The active substance is desogestrel.  
Each film coated tablet contains 75 microgram desogestrel.

The other excipients are: lactose monohydrate, maize starch, povidone K30, silica colloidal hydrated, silica colloidal anhydrous, RRR-α-tocopherol, stearic acid, hypromellose 2910, macrogol 400, titanium dioxide (E171), refined soya-bean oil.

What Desogestrel Rowex looks like and contents of the pack

Desogestrel Rowex is a white round film coated tablet with a diameter of approximately 5 mm and a thickness of 2.9 mm approximately, packed in PVC-PVDC/ Al blisters with pack sizes of 1x28, 3x28, 6x28 and 13x28.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH., Otto-von-Guericke-Allee 1, Sachsen-Anhalt, 39179 Barleben, Germany.  
Laboratorios León Farma S.A. , C/La Vallina s/n, Pol. Ind. Navatejera 24008, Navatejera – León, Spain.

This medicinal product is authorized in the Member States of the EEA under the following names:

Austria	Desogestrel Sandoz 75 Mikrogramm – Filmtabletten
Belgium	Saphirena 75 microgram filmomhulde tabletten
Czech Republic	Daisenette Neo 75 mikrogramů
Denmark	Delamonie
Germany	Chalant® HEXAL® 75 Mikrogramm Filmtabletten
Estonia	Delamonie
Finland	Delamonie 75 mcg tabletti, kalvopäällysteinen
France	DESOGESTREL SANDOZ 0,075 mg, comprimé pelliculé
Italy	Desantrel
Ireland	Desogestrel Rowex 75 microgram Film-coated tablets
Lithuania	Delamonie 75 mikrogramai plėvele dengtos tabletės
Luxembourg	Saphirena 75 microgrammes comprimés pelliculés
Latvia	Delamonie 75 mikrogramu apvalkotās tabletes
Netherlands	Delamonie 75 microgram, filmomhulde tabletten
Norway	Delamonie 75 mikrogram tablett, filmdrasjert
Poland	Desandrelle
Portugal	Delamonie
Romania	Desogestrel Sandoz 75 micrograme comprimate filmate
Slovenia	Delamonie 75 mikrogramov filmsko obložene tablete
Slovakia	Desogestrel Sandoz

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