Package leaflet: Information for the patient

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
3. How to take Desogestrel Rowex
4. Possible side effects
5. How to store Desogestrel Rowex
6. Contents of the pack and other information

1. What Desogestrel Rowex is and what it is used for

- Desogestrel Rowex is used to prevent pregnancy.
- There are 2 main kinds of hormone contraceptive.
  - The combined pill, "The Pill", which contains 2 types of female sex hormone, an oestrogen and a progestogen,
  - The progestogen-only pill, POP, which doesn't contain an oestrogen.
- Desogestrel Rowex is a progestogen-only-pill (POP).
- Desogestrel Rowex contains a small amount of one type of female sex hormone, the progestogen **desogestrel**.
- 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 main way that combined pills work.
- Desogestrel Rowex is different from most POPs in having a dose that in most cases prevents the egg cell from ripening. As a result, Desogestrel Rowex is a highly effective contraceptive.
- 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, to peanut or soya, 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 is still not working normally
- if you have or are suspected of having 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 any of these conditions apply to you, tell your doctor before you start to use Desogestrel Rowex. Your doctor may advise you to use a non-hormonal method of birth control.
If any of these conditions appear for the first time while using Desogestrel Rowex, consult your doctor immediately.

Warnings and precautions

Talk to your doctor, or pharmacist or Family Planning Nurse before taking 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

<u>It is important</u> to regularly check your breasts and you should 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, this reduces the risk, so that 10 years after stopping the Pill, 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 a woman continues to take the Pill when she is older. 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.
- 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 certain whether the Pill causes the increased risk of breast cancer. 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". A pulmonary embolism can cause chest pain, breathlessness, collapse or even death.

- 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).

Psychiatric disorders:
Some women using hormonal contraceptives including Desogestrel Rowex 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.

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, or Family Planning Nurse if you are taking, have recently taken or might take any other medicines. Also tell any other doctor or dentist who prescribes another medicine that you take Desogestrel Rowex. 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 Rowex.

- 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, nelfinavir, nevirapine, 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 Rowex less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Desogestrel Rowex 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 Rowex may also interfere with how other medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect (lamotrigine).

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

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 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 Rowex 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 pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Desogestrel Rowex has no known effect on the ability to drive or use machines.

Desogestrel Rowex 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
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 notice possible signs of a **blood clot** e.g. 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 **jaundice** (you may notice yellowing of the skin, the whites of the eyes, or dark urine, possibly a sign of **liver problems**)
- you feel a lump in your **breast** (possibly a sign of **breast cancer**)
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly a sign of an **ectopic pregnancy -** 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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When and how to take the tablets?
The Desogestrel Rowex pack contains 28 tablets.
- **Take your tablet each day at about the same time. Swallow the tablet whole, with water**.
- 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 strip 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 (on 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.

You may have some bleeding during the use of Desogestrel Rowex, (see section 4 'Side Effects') but you must continue to take your tablets as normal.

When a strip is empty, you must start with a new strip of Desogestrel Rowex on the next day – without interruption and without waiting for a bleed.

Starting your first pack of Desogestrel Rowex

- If you are not using hormonal contraception at present (or in the past month):

Wait for your period to begin. On the first day of your period take the first Desogestrel Rowex tablet. Additional contraceptive precautions are not necessary.
If you take your first tablet on days 2-5 of your period use an additional barrier method of contraception for the first 7 days of tablet-taking.

- When you change from a combined pill (COC), vaginal ring, or transdermal patch:

If you don't have a tablet-, ring- or patch-free break

- 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 (placebo) 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, additional contraceptive precautions are not necessary.

If you have a tablet-, ring- or patch-free break

- You can also start on the day following the tablet-, ring-, patch-free break, or when you have taken all the inactive (placebo) tablets, of your present contraceptive.
- **If you follow these instructions, make sure you use an additional barrier method of contraception for the first 7 days of tablet-taking.**
- **When changing from another progestogen-only pill:**
- Switch on any day from another mini-pill. Additional contraceptive precautions are not necessary.
- When changing from an injection or implant or a hormonal intrauterine device system (IUS):
- Start using Desogestrel Rowex when your next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive precautions are not necessary.
- **After you have 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 barrier method of contraception until you have completed the first 7 days of tablet-taking. However, if you have already had sex, check that you are not pregnant before starting Desogestrel Rowex. Information for breast-feeding women can be found in section 2 'Before you take Desogestrel Rowex' in the paragraph 'Pregnancy and breast-feeding'. 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:
- Take the missed tablet as soon as you remember and take the next one at the usual time. Desogestrel Rowex will still protect you from pregnancy.
- If you are **more than 12 hours** late:
  - If you are more than 12 hours late in taking any tablet, **you may not be completely protected against pregnancy.** The more consecutive tablets you have missed, the higher the risk that

you might fall pregnant.

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

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.
Tell your doctor if you notice any unwanted effect, especially if severe or persistent.

Serious side effects associated with the use of Desogestrel Rowex are described in section 2 "What you need to know before you take Desogestrel Rowex". Please read this section for additional information on 'Breast cancer' and 'Thrombosis' and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals while using 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. You may need to use tampons or sanitary towels. You may also not have any bleeding at all. Irregular bleeding is not a sign that Desogestrel Rowex is not working. In general, you need not take any action; just continue to take Desogestrel Rowex. **If bleeding is heavy or prolonged you should consult your doctor.**

How often are other possible side effects seen?

Common: may affect up to 1 in 10 people

- mood changes
- depressed mood
- decreased sexual drive (libido)
- headache
- nausea
- acne
- breast pain
- irregular or no periods
- weight increase.

Uncommon: may affect up to 1 in 100 people

- infection of the vagina
- difficulties in wearing contact lenses
- vomiting
- hair loss
- painful periods
- ovarian cysts
- tiredness.

Rare: may affect up to 1 in 1,000 people

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 (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 Family Planning Nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: for Ireland via HPRA Pharmacovigilance; website: www.hpra.ie. For Malta, you can also report side effects via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.
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 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 store above 30ºC. Store in the original package in order to protect from light.

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.

Environmental Risk Assessment (ERA)
The active substance etonogestrel shows an environmental risk to fish.

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 Polígono Industrial de Navatejera 24193 Villaquilambre, León, Spain

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

Denmark	Delamonie
Czech Republic	Daisenette Neo 75 mikrogramů
Germany	Chalant® HEXAL® 75 Mikrogramm Filmtabletten
Estonia	Delamonie
France	DESOGESTREL SANDOZ 75 microgrammes, comprimé pelliculé
Italy	Desantrel
Ireland	Desogestrel Rowex 75 microgram Film-coated tablets
Malta	Desogestrel Rowex 75 microgram Film-coated tablets
The Netherlands	Delamonie 75 microgram, filmomhulde tabletten
Norway	Delamonie 75 mikrogram tablett, filmdrasjert

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