

DESIRETT 75mcg film-coated tablets

Desogestrel 75 µg film-coated tablets

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1. WHAT DESIRETT IS USED FOR

DESIRETT is used to prevent pregnancy.

2. HOW DESIRETT WORKS

It works 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.

3. BEFORE YOU TAKE DESIRETT

When you must not use it

- If you are allergic to any of the ingredients of **DESIRETT**.
- 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.

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

Before you start to use it

Tell your doctor before you start to use **DESIRETT**, if

- you have ever had cancer of the breast.
- you have liver cancer, since a possible effect of **DESIRETT** 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 or ultraviolet radiation.

When **DESIRETT** 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.

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 **DESIRETT** 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.

DESIRETT may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

4. HOW TO USE DESIRETT

How much to use

Tablets must be taken every day at about the same time with some liquid as needed. One tablet is to be taken daily for 28 consecutive days. Each subsequent pack is started immediately after finishing the previous pack.

Starting your first pack of Desirett

- 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 Desirett tablet. Additional contraceptive precautions are not necessary. If you take your first tablet on days 2-5 of your period use an additional

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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 Desirett 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 Desirett 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- or 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 IUS:
Start using Desirett 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 Desirett between 21 to 28 days after the birth of your baby. If you start later, make sure that you use an additional barrier method of contraception until you have completed the first 7 days of tablet-taking. However, if you already had sex, check that you are not pregnant before starting Desirett.

Your doctor can also advise you.

- After a miscarriage or an abortion:
Your doctor will advise you.

When to use it
Take your tablet each day at about the same time. Swallow the tablet whole, with water.

How long to use it
Your doctor may prescribe **DESIRETT** for long periods, until you no longer need or want contraception.

If you forget to use it
If you are **less than 12 hours** late in taking a tablet, the reliability of **DESIRETT** 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 **DESIRETT** 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 use too much (Overdose)
There are no mention of seriously damaging results of taking too many **DESIRETT** 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.

5. WHILE YOU ARE USING DESIRETT

Things you must do

While you are using **DESIRETT** 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 in 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 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

Things you must not do

Avoid smoking as it increase the risk of thrombosis.

If you are pregnant, you must not take **DESIRETT**. If you become pregnant while taking **DESIRETT** you must stop immediately and contact your doctor.

Things to be careful of

If you experience any unusual symptoms when you are taking **DESIRETT**, please consult your healthcare professionals immediately.

6. SIDE EFFECTS

The common side effects are: mood altered, decreased sexual drive (libido), headache, nausea, acne, breast pain, irregular or no menstruation, increased body weight.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nptra.moh.gov.my (Public → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

7. STORAGE AND DISPOSAL OF DESIRETT

Keep out of sight and reach of children.

Do not store above 30°C. Keep in a cool and dry place.

Do not use **DESIRETT** 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 waste-water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. PRODUCT DESCRIPTION

What it looks like

One blister pack of **DESIRETT** contains 28 round, plain, white tablets.

Ingredients

The active substance is: desogestrel (75 microgram)

The other ingredients are: lactose monohydrate, maize starch, povidone K30, RRR- α -tocopherol, silica colloidal anhydrous, silica colloidal hydrated, stearic acid, hypromellose, polyethylene glycol, titanium dioxide (E 171)

Product Registration Number

MAL17025025ACZ

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer

LABORATORIOS LEON FARMA, S.A.
La Vallina s/n
Poligono Industrial
Navatejera, 24008 Leon,
Spain

Product Registration Holder

Eurodrug Laboratories (M) Sdn Bhd
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