

Package leaflet: Information for the user

Cerelle 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.

What is in this leaflet

1. What Cerelle 75 microgram film-coated tablets (hereafter: Cerelle) is and what it is used for
2. What you need to know before you take Cerelle
3. How to take Cerelle
4. Possible side effects
5. How to store Cerelle
6. Contents of the pack and other information

1. What Cerelle is and what it is used for

This medicine is for the prevention of pregnancy.

How does it work?

Cerelle contains a small amount of one type of female sex hormone, the progestogen, desogestrel. For this reason Cerelle is called a progestogen-only pill (POP) or mini-pill. Unlike the combined pill, the POP or mini-pill does not contain an oestrogen hormone, but only a progestogen. Most POPs or mini-pills 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.

Cerelle 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, Cerelle provides high contraceptive efficacy. In contrast to the combined pill, Cerelle 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 Cerelle. You also may not have any bleeding at all.

2. What you need to know before you take Cerelle

Cerelle will not protect you against HIV infection (AIDS) and any other sexually transmitted diseases.

Do not take Cerelle

Do not use Cerelle if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use Cerelle. Your doctor may advise you to use a non-hormonal method of birth control.

- If you are allergic to desogestrel or any of the other ingredients of this medicine (listed in section 6.).

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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 Cerelle 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 Cerelle

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

Some medicines may stop the pill 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, rifabutin),
- HIV infection (e.g. ritonavir, nelfinavir),
- fungal infections (e.g. griseofulvin),
- medical charcoal used for stomach upset,
- products containing St. John's Wort (Hypericum perforatum).

Your doctor can tell you if you need to take additional contraceptive precautions and if so, how long.

Cerelle 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, breast-feeding and fertility

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

Cerelle is not indicated if you are pregnant, or think you may be pregnant.

Cerelle may be used while you are breast-feeding. Cerelle does not influence the production or the quality of breast milk. However, a small amount of the active substance of Cerelle 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 breast feeding and want to use Cerelle, please contact your doctor.

Driving and using machines

Cerelle has no influence on the ability to drive and use machines.

Cerelle contains lactose

In case of milk sugar (lactose) intolerance it should be considered that each Cerelle tablet also contains 52.34 mg lactose (as lactose monohydrate).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Regular check-ups

When you are using Cerelle, 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.

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- If you have thrombosis. Thrombosis is the formation of a blood clot in a blood vessel, which may lead to obstruction of this blood vessel (e.g. of the legs (deep venous thrombosis), the lungs (pulmonary embolism).
 - If you have or have had a severe liver disease and the function of your liver (as determined by laboratory investigation of the blood) has not returned to normal.
 - If you have cancer that grows under the influence of certain hormones (progestagens), such as certain types of breast cancer.
 - If you have any unexplained vaginal bleeding.
- If any of these conditions appears for the first time while using Cerelle you should consult your doctor promptly.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cerelle.

If Cerelle is used in the presence of any of the conditions listed below, you may need to be kept under close observation.

Your doctor can explain to you what to do. Therefore if any of these apply to you, tell your doctor before starting to use Cerelle:

- you have or have ever had breast cancer;
- you have cancer of the liver;
- you have or ever had venous thromboembolism;
- you have diabetes;
- you suffer from epilepsy (see section "Other medicines and Cerelle");
- you suffer from tuberculosis (see section "Other medicines and Cerelle");
- 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.

Breast cancer

Check your breasts regularly 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 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 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 progestogen-only pills like Cerelle 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").

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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**.

3. How to take Cerelle

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

Each strip of Cerelle contains 28 tablets. Arrows and the days of the week are printed on the front side of the strip, which help you take your pill correctly. Take your daily tablet at about the same time each day. Swallow each tablet whole with water.

Every time you start a new strip of Cerelle take a tablet from the top row. For example, if you start on a Wednesday, you should take the tablet from the top row marked WE. You should continue to take one tablet a day, until the strip is empty, always following the direction indicated by the arrows. Remember to use any remaining tablets from the first row, in sequence, before starting a new strip. In this way you can easily check whether you have taken your daily tablet. You may have some bleeding during the use of Cerelle (see section 4. "Possible side effects"), but you must continue to take your tablet as normal.

When a strip is empty, you must start with a new pack of Cerelle on the next day – without interruption and without waiting for a bleeding.

Starting your first pack of Cerelle

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 Cerelle 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 Cerelle preferably 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 Cerelle 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.

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When changing from another progestogen-only pill (mini-pill).

You may stop taking it any day and start taking Cerelle 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 Cerelle 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 Cerelle 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) for the first 7 days of tablet-taking during the first cycle. However, if intercourse has already occurred, pregnancy should be excluded before starting Cerelle use. Additional information for breast-feeding women can be found in 'Pregnancy, breast-feeding and fertility' 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 one or more tablets

If you are less than 12 hours late

Take the tablet as soon as you remember, and take the next one at the usual time. The contraceptive action of Cerelle is maintained.

If you are more than 12 hours late

Take a tablet as soon as you remember, and take the next one at the usual time. This may mean taking two tablets on the same day. This is not harmful. (If you have forgotten more than one tablet you don't need to take the earlier missed ones). You are not protected against pregnancy. Continue to take your tablets as usual, but you must use an extra method, such as a condom for the next 7 days.

The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.

If you missed one or more tablets in the first week of tablet-intake and had sex in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

If you vomit, have diarrhoea or use medical charcoal

If you vomit or use medical charcoal within 3 - 4 hours after taking the pill or have severe diarrhoea, the active substance may not have been completely absorbed. Follow the advice for missed tablets above.

If you take more Cerelle than you should

There have been no reports on serious harmful effects from taking too many Cerelle 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 Cerelle

You can stop taking Cerelle 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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Serious undesirable effects associated with the use of Cerelle are described in section 2 "What you need to know before you take Cerelle". 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 during the use of Cerelle. 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. Irregular bleeding is not a sign that the contraceptive protection of Cerelle is decreased. In general, you need not take any action; just continue to take Cerelle. If, however, bleeding is heavy or prolonged you should consult your doctor.

Users of desogestrel have reported the following side effects:

Common (may affect up to 1 in 10 people):

- mood altered,
- decreased sexual drive (libido),
- depressed mood,
- headache,
- nausea,
- acne,
- breast pain,
- irregular or no menstruation,
- increased body weight.

Uncommon (may affect up to 1 in 100 people):

- infection of the vagina,
- difficulties in wearing contact lenses,
- vomiting,
- hair loss,
- painful menstruation,
- ovarian cyst,
- tiredness.

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

- rash,
- hives,
- painful blue-red skin lumps (erythema nodosum) (these are skin conditions).

Apart from these side effects, breast secretion may occur.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Cerelle

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

Store in the original package in order to protect from light and moisture.
This medicinal product does not require any special temperature storage conditions.

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

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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 Cerelle contains

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

- The other ingredients are:

Tablet core:
Lactose monohydrate,
Potato starch,
Povidone K-30,
Silica, colloidal anhydrous,
Stearic acid,
all-rac- α -tocopherol

Tablet coat:
Poly(vinyl alcohol),
Titanium dioxide (E171),
Macrogol 3000,
Talc

What Cerelle looks like and contents of the pack

Cerelle is white or almost white, round, biconvex film-coated tablet of about 5.5 mm in diameter, with a sign "D" on one side and "75" on the other side.

Cerelle film-coated tablets are packed in PVC/PVDC-Aluminium blister, in a laminated aluminium sachet and cardboard cartons with a leaflet and etui storing bag enclosed.

Pack sizes: 1x28, 3x28 film-coated tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Gedeon Richter Plc.
Gyömrői út 19-21
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Manufacturer

Gedeon Richter Plc.
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This leaflet was last revised in 08/2012.

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