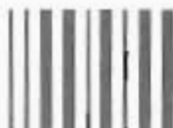


# Cerazette®

Tablets



## User package leaflet for Cerazette

Please read this page carefully before you start using Cerazette. This leaflet will provide information about the benefits and risks of Cerazette. It will also advise you about how to take Cerazette properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

### What is Cerazette?

#### What does it contain?

One pack of Cerazette contains 28 white round tablets. Each tablet contains:

- active ingredient: desogestrel (75 microgram)
- other ingredients: silica, colloidal anhydrous;  $\alpha$ -tocopherol; lactose monohydrate; maize starch; povidone; stearic acid. Each tablet is covered with a thin coating of hypromellose; macrogol 400; talc and titanium dioxide (E 171).

#### How does it work?

Cerazette contains a small amount of one type of female sex hormone, the progestagen desogestrel. For this reason Cerazette is called a progestagen-only-pill (POP), or a mini-pill. Contrary to combined pills, mini-pills do not contain an estrogen hormone next to the progestagen. Most mini-pills work primarily by preventing the sperm cells from entering the womb but, unlike combined pills, they do not always prevent an egg cell from ripening. Cerazette is distinct from other mini-pills because, like combined pills, in most cases it does prevent the egg cells from ripening. As a result, Cerazette provides high contraceptive efficacy. In contrast to the combined pill, Cerazette can be used by women who do not tolerate estrogens and by women who give breast feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Cerazette. You also may not have any bleeding at all.

#### Why is it used?

To prevent pregnancy. When Cerazette is taken correctly (without missing tablets), the chance of becoming pregnant is very low.

#### When should you not use Cerazette?

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

- 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 jaundice (yellowing of the skin) or severe liver disease.
- If you have a cancer that grows under the influence of progestagens.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are allergic to any of the ingredients of Cerazette.

If any of these conditions appear for the first time while using Cerazette you should consult your doctor promptly.

#### What do you need to know before and during treatment with Cerazette?

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

#### Before you start to use Cerazette

If Cerazette 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 Cerazette:

- you have or have had cancer of the breast;
- you have cancer of the liver;
- you have ever had a thrombosis;
- you have diabetes;
- you suffer from epilepsy;
- you suffer from tuberculosis;
- 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.

#### Potentially serious conditions

##### Decreased Bone Mass

Estrogens are important to maintain the strength of your bones. During the use of Cerazette, the concentration in your blood of the natural estrogen estradiol is comparable to the concentration seen in the first half of your natural cycle but is decreased in comparison with the second half of the natural cycle. It is not known whether this has an effect on the strength of your bones.

##### Breast Cancer

Every woman is at risk of breast cancer whether or not she takes oral contraceptives ('the Pill'). 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. When 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 among women who use the Pill at a higher age. How long a woman 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. 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

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, but it is not as high as the risk during pregnancy. The risk with progestagen-only pills like Cerazette is believed to be lower than in users of Pills that also contain estrogens (combined Pills). If you notice possible signs of a thrombosis, you should see your doctor immediately. (See also 'When should you contact your doctor?')

##### The use of other Medicines

Some medicines may stop Cerazette from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, hydantoins, barbiturates) or tuberculosis (e.g. rifampicin, rifabutin). Always tell the doctor, who prescribes Cerazette, which medicines you are already using.

##### Vaginal Bleeding

Vaginal bleeding may occur at irregular intervals during the use of Cerazette. 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 Cerazette is decreased. In general, you need not take any action; just continue to take Cerazette. If, however, bleeding is heavy or prolonged consult your doctor.

##### Ovarian Cysts

During the use of all low-dose

hormonal contraceptives, small fluid-filled sacs may develop in the ovaries. These are called ovarian cysts. They usually disappear on their own. Sometimes they cause mild abdominal pain. Only rarely, they may lead to more serious problems.

#### **Pregnancy**

Cerazette must not be used by women who are pregnant, or who think they may be pregnant.

#### **Breast feeding**

Cerazette does not influence the production or the quality of breast milk. Small amounts of the active substance in Cerazette pass over in breast milk. As a result, 0.01 to 0.05 microgram per kg body weight per day may be ingested by the baby, but there are no indications of any risk. Tell your doctor if your baby shows any signs or symptoms which you think might be related to the use of Cerazette.

#### **Ability to drive**

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

#### **When should you contact your doctor**

##### **Regular check-ups**

When you are using Cerazette, 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 thrombosis (e.g. severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially if you cough up blood);
- you have a sudden, severe stomach ache or look jaundiced (indicating possible liver problems);
- you feel a lump in your breast;
- you have a sudden or severe pain in the lower part of your belly or the stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- you are to be immobilised (for example being confined to bed) 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.

#### **How do you use Cerazette?**

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

The Cerazette pack contains 28 tablets. Next to each tablet is printed the day on which that particular tablet is to be taken. Take your tablet at about the same time each day. Swallow each tablet whole, with water. Each time you start a new pack of Cerazette, take a tablet in the top row. You continue to take one tablet a day

until the pack is empty, always following the direction indicated by the arrows. In this way you can easily check whether you have taken your daily tablet. You may have some bleeding during the use of Cerazette, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of Cerazette on the next day - thus without interruption and without waiting for a bleed.

You can stop taking Cerazette whenever you want. Contraception finishes on the day of stopping Cerazette.

#### **Starting your first pack of Cerazette**

*If you are not taking the pill at present*  
Wait for your period to begin. On the first day of your period take the first Cerazette tablet. You need not take extra contraceptive precautions.

*When you change from a combined pill*  
You can start taking Cerazette on the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains inactive tablets you can start Cerazette on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist).

*When you change from another mini-pill*

You may stop taking it any day and start taking Cerazette right away. You need not take extra contraceptive precautions.

*When you change from an injectable or implant*

Start using Cerazette when your next injection is due or on the day that your implant is removed. You need not take extra contraceptive precautions.

*If you have just had a baby 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 in taking a tablet, the reliability of Cerazette 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 Cerazette 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 a condom 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 vomit**

If you vomit within 3-4 hours after

taking your Cerazette tablet, the active ingredient may not have been completely absorbed. Follow the advice for missed tablets.

#### **If too many Cerazette tablets are taken (overdose)**

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

#### **When you want to stop taking Cerazette**

You can stop taking Cerazette at any time you want, if you do not want to become pregnant, ask your doctor about other methods of birth control. If you stop using Cerazette because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

#### **What side effects might you have while taking Cerazette?**

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by Cerazette.

##### **Serious Side Effects**

Serious undesirable effects associated with the use of contraceptive Pills are described in 'What do you need to know before and during the use of Cerazette?' Please read this section for additional information and consult your doctor at once where appropriate.

##### **Other possible Side Effects**

Some common side effects reported by users of Cerazette are: acne, breast pain, decreased libido, headache, irregular vaginal bleeding, mood changes, nausea, and weight increase. Less common or rare are difficulties in wearing contact lenses, hair loss, infection of the vagina, painful menses, tiredness, various skin reactions, vomiting. Contact your doctor if you have any other complaints that you cannot explain but think might be due to Cerazette.

##### **Storage Instructions**

Do not use after the expiry date stated on the package.

**Keep your tablets out of reach of children!**

##### **Manufacturer**

Cerazette is produced by NV Organon, P.O. Box 20, 5340 BH Oss, The Netherlands

In correspondence please quote packing number

