

Package leaflet: information for the user
Cerazette, 75 microgram film-coated tablets
desogestrel

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It can be harmful to others.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Contact your doctor or pharmacist.

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1. What is Cerazette and what is it used for?

Cerazette is used to prevent pregnancy. Cerazette contains a small amount of one type of female sex hormone, the progestogen desogestrel. Therefore, Cerazette is also called a progestogen-only pill. Progestogen-only pills contain – unlike combination pills – no estrogen hormone alongside the progestogen. The action of most progestogen-only pills is mainly based on the fact that they prevent

sperm cells from entering the uterus. The maturation of an egg is not always inhibited. This latter is the main action of the combination pill. Cerazette differs from most progestogen-only pills because the dose is high enough to prevent egg maturation in most cases. Therefore, Cerazette is very reliable. Unlike combination pills, Cerazette can be used by women who do not tolerate

estrogens and by women who are breastfeeding. A disadvantage of Cerazette is that the monthly bleeding from the vagina may occur at irregular intervals. There is also a chance that this bleeding will not occur at all. 2. When should you not take this medicine or be extra careful with it?

Like other hormonal contraceptives, Cerazette does not protect against HIV infection (AIDS) or any

other sexually transmitted disease (STD). When should you not take this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in

- section 6. section 6.

- You have thrombosis. Thrombosis is the formation of a blood clot in a blood vessel (for example in a leg (deep vein thrombosis) or in the lungs (pulmonary embolism)).
- You have jaundice (yellowing of the skin) or a severe liver disease, or you have had this, and your liver function is not yet normal.
- You have a form of cancer that is sensitive to sex hormones, such as some types of breast cancer, or there is a suspicion that you have this.
- You have unexplained vaginal bleeding.

Tell your doctor before you start taking Cerazette if any of these situations apply to you. Your doctor may then recommend a non-hormonal method of birth control. Contact your doctor immediately if any of these situations occur while you are using Cerazette. used.

Tell your doctor before you start treatment with Cerazette, if:

You have ever had breast cancer.

- You have liver cancer, because a possible effect of Cerazette cannot be excluded.
- You have ever had thrombosis.
- You have diabetes.
- You have epilepsy (see the section 'Are you taking any other medicines?').
- You have tuberculosis (see the section 'Are you taking any other medicines?').
- You have high blood pressure.
- You have high blood pressure.
- You have chloasma or have ever had it (yellow-brown pigment spots on the skin, so-called 'pregnancy spots', especially on the face); if this is the case, then avoid direct exposure to sunlight or ultraviolet light.

If Cerazette is used while you have any of these conditions, it may be necessary for you to remain under extra monitoring. Your doctor can explain what you need to do.

Breast cancer

It is important to regularly check your breasts and contact your doctor immediately if you feel a lump in your breasts.

Breast cancer is diagnosed slightly more often in women who use the pill than in non-pill users of the same age. If women stop using the pill, the risk gradually decreases, so that 10 years after stopping it is the same as for women who have never used the pill. Breast cancer is rare below the age of 40, but the risk increases with age. Therefore, the number of extra diagnosed cases of breast cancer is higher among women who use the pill until an older age. How long the pill is used is less important.

For every 10,000 women who use the pill for 5 years but stop when they are 20 years old, up to 10 years after stopping, less than 1 extra case of breast cancer would be found, in addition to the 4 cases that are normally diagnosed in this age group. Similarly, for every 10,000 women who use the pill for 5 years but stop when they are 30 years old, 5 extra cases of breast cancer would be found, in addition to the 44 cases that are normally diagnosed.

In 10,000 women who use the pill for 5 years but stop when they are 40 years old, there would be 20 extra cases of breast cancer found, in addition to the 160 cases that are normally

diagnosed. It is thought that the risk of breast cancer in users of progestogen-only pills, such as Cerazette, is comparable to the risk in users of the combined pill, but the evidence, for this is less convincing.

The cases of breast cancer found in pill users are often less advanced than those in non-pill users. It is not known whether the difference in breast cancer risk is caused by the pill. It may also be that pill users are examined more often so that the breast cancer is detected earlier.

Thrombosis

Contact your doctor immediately if you experience symptoms that may indicate thrombosis (see also 'Regular check-up').

Thrombosis is the formation of a blood clot that can block a blood vessel. Thrombosis sometimes occurs in one of the deep veins of the leg (deep vein thrombosis). If the clot breaks loose, it can travel to the arteries of the lungs and block a blood vessel there (pulmonary embolism). This can sometimes be fatal. Deep vein thrombosis is rare. It can occur in pill users and non-pill users. It can also occur during the pregnancy.

The risk of thrombosis is higher in users of the combination pill than in non-pill users. The risk with progestogen-only pills, such as Cerazette, is considered lower than in users of combination pills that also contain estrogens.

Psychiatric disorders

Some women using hormonal contraceptives including Cerazette have reported depression or low mood. Depression can be severe and may sometimes lead to suicidal thoughts. If you experience mood changes and symptoms of depression, contact your doctor as soon as possible for further medical advice.

Children and adolescents up to 18 years

There is no research information on the efficacy and safety in adolescents under 18 years.

Are you using any other medicines?

Are you using any other medicines or herbal remedies besides Cerazette, have you done so recently, or is there a possibility that you will use other medicines in the near future? Tell your doctor or pharmacist. Also inform any other doctor or dentist who prescribes you another medicine (or your pharmacist) that you are using Cerazette. They can tell you if you need to take extra contraceptive measures (e.g., condoms) and for how long, or if the use of your other medicine needs to be changed.

Some medications

- can affect the blood levels of Cerazette
- can make Cerazette less effective in preventing pregnancy
- can cause unexpected bleeding.

These include medications 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)
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 using medications or herbal remedies that can make Cerazette less effective, you should also use a barrier contraceptive method. Since the effect of another medication on Cerazette can last up to 28 days after stopping that medication, you should continue using that additional barrier contraceptive method during that time. Your doctor can tell you if and how long you need to use additional contraceptive measures.

Cerazette can also affect the action of other medicines and enhance the effect (for example, medicines with cyclosporine) or reduce it (for example, lamotrigine).
Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy and breastfeeding

Pregnancy

Do not use Cerazette if you are pregnant or think you might be pregnant.

Breastfeeding

Cerazette can be used while you are breastfeeding. Cerazette appears to have no effect on the production or quality of breast milk. However, there are a small number of reports of a decrease in breast milk production during the use of Cerazette. A small amount of the active substance of Cerazette passes into breast milk.

The health of children who were breastfed for 7 months and whose mothers used Cerazette was studied for 2.5 years. No effect on the growth or development of the children was observed.

If you are breastfeeding and want to use Cerazette, contact your doctor.

Driving and using machines

There is no evidence that concentration and reaction ability are affected by the use of Cerazette.
Cerazette contains lactose

Cerazette contains lactose

Contact your doctor before taking Cerazette if your doctor has told you that you cannot tolerate certain sugars.

Regular check-up

Your doctor may advise you to make regular appointments for a medical check-up if you use Cerazette. How often you need to return for a check-up and what examinations take place depends on your personal situation. return and what examination then takes place.

Contact your doctor as soon as possible in the following cases:

- in case of severe pain or swelling in one of the legs, unexplained chest pain, shortness of breath,
- sudden unusual coughing, especially if it is accompanied by coughing up blood (this may indicate thrombosis)
- in case of sudden, severe abdominal pain or jaundice (this may indicate liver problems)
- in case of a lump in the breast (this may indicate breast cancer)
- in case of sudden, severe pain low in the abdomen or in the stomach area (this may indicate an ectopic pregnancy)
- at least four weeks before you have to undergo surgery or when you are bedridden for some time or are not allowed to walk
- in case of unexplained, severe and persistent vaginal bleeding
- if you suspect you might be pregnant.

3. How do you take this medicine?

When and how do you take the tablets?

The Cerazette strip contains 28 tablets. On the front of the strip, between the tablets, you will see arrows. On the foil on the back, the days of the week are printed. Each day corresponds to a tablet. Start each new strip with a tablet from the top row. Make sure you start with the correct tablet. For example, if you start on Wednesday, take the tablet from the top row where (on the back) WED is indicated. Follow the direction of the arrows and take one tablet each day until the strip is empty. On the back of the strip, you can easily see if you have already taken your daily tablet.

Take the tablets at approximately the same time every day, with some water without chewing. During the use of Cerazette, you may experience some bleeding similar to menstruation, but you should continue taking your tablets as usual. When the strip is empty, start the next day with a new Cerazette strip immediately - without interruption and without waiting for a bleed.

When to start the first strip of Cerazette?

You have not used a contraceptive pill in the past month:

Wait for your menstruation. Take the first Cerazette tablet on the first day of your menstruation. You do not need to use an additional contraceptive. You may also start on days 2-5 of your menstruation, but in this case, you must use an additional contraceptive (a condom) during the first 7 days of tablet use.

You are switching from a combination pill, vaginal ring, or transdermal patch:

Start Cerazette on the day after you have taken the last tablet of your current pill pack or on the day of removal of your vaginal ring or patch (thus without a tablet-, ring-, or patch-free period). If your current pill pack also contains placebo tablets (thus without hormones), you should start Cerazette on the day after you have taken the last active tablet (if you are not sure which this is,

ask your doctor or pharmacist for advice). You do not need to use an additional contraceptive if you follow these instructions.

You may also start at the latest on the day after your tablet-, ring-, or patch-free period or period with placebo tablets of your current contraceptive. If you follow these instructions, you must use an additional contraceptive (a condom) during the first 7 days of tablet use.

Switching from another progestogen-only pill:

You can switch to Cerazette from one day to the next and do not need to use an additional contraceptive.

Switching from an injectable, implant, or hormone-releasing IUD:

You can start Cerazette on the day the next injection is due or on the day your implant or hormone-releasing IUD is removed. You do not need to use an additional contraceptive.

After childbirth:

Start Cerazette between 21 to 28 days after childbirth. If you start later, you must use an additional contraceptive (a condom) during the first cycle until you have taken a tablet for 7 consecutive days. If you have already had sexual intercourse, you must pregnancy should be excluded before you start with Cerazette. Additional information for women who are breastfeeding can be found under 'Pregnancy and breastfeeding' in section 2. Your doctor can also advise you.

After a miscarriage or an abortion:

Follow your doctor's advice.

Did you forget to take this medicine?

If you are less than 12 hours late in taking a tablet, the reliability of Cerazette is not reduced. Take the missed tablet as soon as you remember and take the next tablets at the usual time.

If you are more than 12 hours late in taking a tablet, the reliability of Cerazette may be reduced. The more tablets you have missed in a row, the greater the chance that the contraceptive effect is reduced. Take the last missed tablet as soon as you remember and take the next tablets at the usual time. Also use a condom during the first 7 days of tablet intake. If you have missed one or more tablets in the first week of the strip and you have had intercourse in the 7 days prior to the missed tablets, you should consider the possibility of pregnancy. Ask your doctor for advice.

What to do if you have gastrointestinal disorders (e.g., vomiting, severe diarrhea) Follow the advice given above for forgetting tablets. If you vomit or have severe diarrhea within 3-4 hours after taking a tablet, there is a chance that the active substance is not fully absorbed into the body.

Have you taken too much of this medicine?

There are no reports of serious harmful effects after taking too many Cerazette tablets at once. You may experience nausea and vomiting. In young girls, slight vaginal bleeding may occur. For more information, you may ask your doctor for advice.

If you stop taking this medicine

You can stop taking Cerazette whenever you want. From the day you stop, you are no longer protected against pregnancy.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everyone gets them. to make.

described under 'Breast Cancer' and 'Thrombosis' in section 2. You can read this part for more information and contact your doctor if necessary. information and contact your doctor if necessary.

Contact your doctor immediately if you have a severe reaction from your body due to a severe allergy. You suddenly get: a swollen tongue, swollen lips, a swollen face and/or a swollen throat (angioedema). You may have difficulty breathing or swallowing (angioedema and/or life-threatening allergic reaction). This is life-threatening.

During the use of Cerazette, bleeding from the vagina may occur at irregular intervals. This may be limited to a few drops for which even a panty liner is not needed, or there may be more bleeding, such as a light monthly bleeding, for which you need sanitary pads. There is also a chance that the bleeding will stop completely. Irregular bleeding is not an indication of reduced protection of Cerazette against pregnancy. In general, you do not need to do anything and can continue taking Cerazette. If the bleeding is severe or prolonged, you should contact your doctor. with your doctor.

Common: occur in less than 1 in 10 women
mood swings, depressed mood, decreased libido

headache

nausea

acne

breast pain, you do not have or do not have regular periods

painful breasts, you do not menstruate or do not menstruate regularly

weight gain

Sometimes: occur in less than 1 in 100 women

vaginal infection

eye irritation when using contact lenses

vomiting

hair loss

pain during menstruation, ovarian cyst
fatigue

Rarely: occur in less than 1 in 1000 women

skin rash, rash with pink bumps and severe itching (hives or urticaria), red swelling under the skin. This is due to swelling of the fatty tissue. It is often on your lower leg. The skin is painful (erythema nodosum)

Not known: frequency cannot be determined from the available data
allergic reactions (hypersensitivity)

In addition to these side effects, breast discharge may also occur.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions regarding temperature for this medicine. Keep the blister pack in the original sachet to protect from light and moisture. Use within 1 month after first opening the sachet.

The active substance poses a risk to fish in the environment.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed in a responsible manner and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is desogestrel (75 micrograms).
- The other substances in this medicine are colloidal anhydrous silica, all-rac- α -tocopherol, maize starch, povidone, stearic acid, hypromellose, macrogol 400, talc, titanium dioxide (E171), lactose monohydrate (see also 'Cerazette contains lactose' in section 2).

What does Cerazette look like and what is in a package?

A Cerazette blister pack contains 28 white, round film-coated tablets. On one side of the tablets is 'KV' with '2' below it and on the other side is 'ORGANON*'. Each cardboard box contains 1, 3, 6, or 13 blister packs, each individually packaged in a sachet.

Not all pack sizes may be marketed.

Marketing authorization holder and manufacturer
N.V. Organon, Kloosterstraat 6, 5349 AB Oss, Netherlands.
Tel.: 00800-66550123 (or +32 2 241 81 00)
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Registered under RVG 22743

This medicine is registered in EEA member states under the following names:
Belgium, Denmark, Germany, Finland, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway,
Austria, Portugal, United Kingdom, Sweden: Cerazette
Spain: Cerazet

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