

CERAZETTE[®] TABLETS

Desogestrel (75 microgram)

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What *CERAZETTE* is used for

CERAZETTE is used to prevent pregnancy. *CERAZETTE* contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason *CERAZETTE* is called a progestogen-only-pill (POP), or a mini-pill. Contrary to combined pills, the POP or mini-pill do not contain an estrogen hormone next to the progestogen.

In contrast to the combined pill, *CERAZETTE* can be used by women who do not tolerate estrogens and by women who are 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.

How *CERAZETTE* works

Most POPs or mini-pills work primarily by preventing the sperm cells from entering the womb but, do not always prevent an egg cell from ripening, which is the primary action of combined pills. *CERAZETTE* is distinct from other mini-pills in having a dose that in most cases is high enough to prevent the egg cells from ripening. As a result, *CERAZETTE* provides high contraceptive efficacy.

Before you take *CERAZETTE*

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

- *When you must not take it*

- If you are allergic to any of the ingredients of *CERAZETTE*.
- If you are pregnant or think you might be pregnant.
- If you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel (refer to Section 'Thrombosis').
- If you have had severe liver disease and your liver function is still not normal including jaundice (yellowing of the skin).
- 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.

Tell your doctor before starting to use *CERAZETTE* if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of birth control.

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

- *Before you start to take it*

Tell your doctor before you start to use *CERAZETTE* if you:

- have ever had breast cancer;
- have liver cancer or liver function problem.
- have ever had a thrombosis;
- have diabetes;
- have high blood pressure;
- 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 *CERAZETTE* 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.

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

Regularly check your breasts 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 combined pill than in women of the same age who do not take the combined pill. If women stop taking the combined pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the combined pill. 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 combined pill is higher. How long she takes the combined pill is less important.

The risk of breast cancer in users of progestogen-only pills like *CERAZETTE* is believed to be similar to that in women who use the combined pill, but the evidence is less conclusive.

Breast cancers found in women who take the combined pill, seem less likely to have spread than breast cancers found in women who do not take the combined pill. It is not known whether the difference in breast cancer risk is caused by the combined 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 'When should you contact your doctor?')

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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 users of Pills that also contain estrogens (combined Pills) than in non-users. It is unknown whether this increased risk is applicable to progestagen-only pills like *CERAZETTE*.

Vaginal bleeding

Vaginal bleeding may occur at irregular intervals during the use of *CERAZETTE*. 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. If bleeding is very frequent and irregular, another contraceptive method should be considered.

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 and breast-feeding

Pregnancy

Do not use *CERAZETTE* if you are pregnant, or think you may be pregnant.

Breast-feeding

CERAZETTE may be used while you are breast-feeding. *CERAZETTE* does not

influence the production or the quality of breast milk. However, a small amount of the active substance of *CERAZETTE* passes over into the milk.

If you are breast feeding and want to use *CERAZETTE*, please contact your doctor.

Driving and using machines

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

Important information about some of the ingredients of *CERAZETTE*

CERAZETTE contains lactose (milk sugar). Please contact your doctor before taking *CERAZETTE*, if you have been told by your doctor that you have intolerance to some sugars.

- 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. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use *Cerazette*.

Some medicines may stop *CERAZETTE* from working properly. 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 infection (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),
- stomach upset (medical charcoal)
- depressive moods (the herbal remedy St. John's wort)

If you are taking medicines or herbal products that might make *CERAZETTE*

less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on *Cerazette* may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive for that long.

CERAZETTE may also interfere with how other medicines work, causing either an increase in effect (e.g. medicines containing ciclosporine) or a decrease in effect (e.g., lamotrigine).

How to take *CERAZETTE*

- How much to take. When to take it. How long to take it

The *CERAZETTE* pack contains 28 tablets. Arrows are printed on the front side of the pack, between the tablets. If you turn over your pack, and look at the back side, you will see the days of the week printed on the foil. Each day corresponds to one tablet.

Every time you start a new pack of *CERAZETTE*, 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 (at 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.

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

Starting your first pack of *CERAZETTE*

- *When no hormonal contraceptive has been used in the past month.*

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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.

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 you change from a combined pill, vaginal ring, or transdermal patch.*

You can start taking *CERAZETTE* on the day after you take the last tablet from your 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 *CERAZETTE* 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 during the first cycle an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

• *When you change from another progestogen-only pill (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 or a progestogen-releasing intrauterine device (IUD).*

Start using *CERAZETTE* 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 *CERAZETTE* between 21 to 28 days after the birth of your baby. If

you start later, make sure you use during the first cycle an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

However, if intercourse has already occurred, pregnancy should be excluded before starting *CERAZETTE* use.

Additional information for breast-feeding women can be found in '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 it*

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 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 diarrhea)

Follow the advice for missed tablets in the section above. If you vomit or use medical charcoal within 3 - 4 hours after taking your *CERAZETTE* tablet or have severe diarrhea, the active ingredient may not have been completely absorbed.

- *If you take too much (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 slight vaginal bleeding. For more information ask your doctor for advice.

- *If you stop taking CERAZETTE*

You can stop taking *CERAZETTE* 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.

While you are using *CERAZETTE*

- *Things you must do*

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.

When should you contact your doctor?

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 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 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

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- Things you must not do

Please refer to section '**Before you take CERAZETTE Pregnancy and breast-feeding**'

- Things to be careful of

Please refer to section '**How to take CERAZETTE. If you forget to take it**' and '**Side effects**'.

Side effects

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

Serious undesirable effects associated with the use of contraceptive Pills are described in the paragraphs "**Breast cancer**" and "**Thrombosis**" in section "**Before you take CERAZETTE**".

Please read this section for additional information and consult your doctor at once where appropriate.

Users of CERAZETTE have reported the following side effects:

Common (occurring in more than one per 100 users) are:

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

Uncommon (occurring in more than one per 1000 users but not more than one per 100 users) are:

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

Rare (occurring in less than one per 1000 users) is:

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

Apart from these side effects, breast secretion may occur.

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: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of CERAZETTE

- Storage

Keep your tablets out of the reach and sight of children!

Store between 2 °C to 30 °C in the original package, in order to protect from light and moisture. Do not use after the expiry date stated on the package.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

One blister pack of Cerazette contains 28 white round biconvex tablets and 5 mm in diameter. The tablets are coded KV above 2 on one side and ORGANON* on the reverse side. Each carton contains 1, 3 or 6 blister packs, each separately packed in a sachet. Not all pack sizes may be available.

- Ingredients

- The active substance is: desogestrel (75 microgram)
- The inactive ingredients are: silica, colloidal anhydrous; all-*rac*- α -tocopherol; maize starch; povidone; stearic acid; hypromellose; macrogol 400; talc; titanium dioxide and lactose monohydrate (see also '**Important**

information about some of the ingredients of CERAZETTE')

- MAL number:

MAL20031939AZ

Product Manufacturer

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Product Registration Holder

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