UNITED KINGDOM USER PACKAGE LEAFLET OF CERAZETTE

Cerazette®
75 microgram film-coated tablets
desogestrel

Read all of this leaflet carefully before you start using 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, please ask your doctor, pharmacist or Family Planning Nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or Family Planning Nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Cerazette is and what it is used for
2. What you need to know before you take Cerazette
   Do not take…
   Warnings and precautions
   Pregnancy and breast-feeding
3. How to take Cerazette
   Starting your first pack
   Changing from other methods
   After a baby
   If you forget to take Cerazette
4. Possible side effects
5. How to store Cerazette
6. Contents of the pack and other information

1. What Cerazette is and what it is used for

- Cerazette is used to prevent pregnancy.
- There are 2 main kinds of hormone contraceptive.
  - The combined pill, **"The Pill"**, which contains 2 types of female sex hormone an oestrogen and a progestogen,
  - The progestogen-only pill, **POP**, which doesn't contain an oestrogen.
- Cerazette is a progestogen-only-pill (POP).
- Cerazette contains a small amount of one type of female sex hormone, the progestogen **desogestrel**.
- Most POPs work primarily by preventing the sperm cells from entering the womb but they do not always prevent the egg cell from ripening, which is the main way that combined pills work.
- Cerazette is different from most POPs in having a dose that in most cases prevents the egg cell from ripening. As a result, Cerazette is a highly effective contraceptive.
- In contrast to the combined pill, Cerazette 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 Cerazette. On the other hand you may not have any bleeding at all.

2. What you need to know before you take Cerazette

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

2.1 Do not take Cerazette

- if you are **allergic** to desogestrel, or any of the other ingredients of Cerazette (listed in section 6).
- 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 is still not working normally.
- if you have or if you are suspected of having a **cancer** that grows under the influence of sex-steroids, such as certain types of breast cancer.
- if you have any unexplained **vaginal bleeding**.

If any of these conditions apply to you, tell your doctor before you start to use Cerazette. Your doctor may advise you to use a non-hormonal method of birth control.
If any of these conditions appear for the first time while using Cerazette, consult your doctor immediately.

2.2 Warnings and precautions

Before you start Cerazette tell your doctor or Family Planning Nurse, if

- you have ever had **breast cancer**.
- you have **liver cancer,** since a possible effect of Cerazette cannot be excluded.
- you have ever had a **thrombosis**.
- you have **diabetes**.
- you suffer from **epilepsy** (see section 'Other medicines and Cerazette').
- you have **tuberculosis** (see section 'Other medicines and Cerazette').
- 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 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.

2.2.1 Breast cancer

- It is important to regularly check your breasts and you should 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, this reduces the risk, 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 a woman continues to take the Pill when she is older. 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.
- 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 of progestogen-only pills like Cerazette 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 certain whether the Pill causes the increased risk of breast cancer. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

2.2.2 Thrombosis
See your doctor immediately if you notice possible signs of a thrombosis (see also 'Regular check-ups').

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". A pulmonary embolism can cause chest pain, breathlessness, collapse or even death.

- 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 Cerazette is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

2.2.3 Psychiatric disorders
Some women using hormonal contraceptives including Cerazette have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

2.3 Children and adolescents
No clinical data on efficacy and safety are available in adolescents below 18 years.

2.4 Other medicines and Cerazette
Tell your doctor, pharmacist, or Family Planning Nurse if you are taking, have recently taken or might take any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take Cerazette. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long or whether the use of another medicine you need must be changed.

Some medicines:
- can have an influence on the blood levels of Cerazette.
- can make it **less effective in preventing pregnancy**.
- can cause unexpected bleeding.

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 infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz);
- Hepatitis C virus infection (e.g. boceprevir, telaprevir);
- or 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 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 method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

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

Ask your doctor or pharmacist for advice before taking any medicine.

2.5 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 appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using Cerazette. A small amount of the active substance of Cerazette passes over into the milk.

The health of children who were breast-fed for 7 months while their mothers were using Cerazette has been studied up until they were 2½ years of age. No effects on the growth and development of the children were observed.

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

2.6 Driving and using machines

Cerazette has no known effect on the ability to drive or use machines

2.7 Cerazette contains lactose

Cerazette contains lactose (milk sugar). Please contact your doctor before taking Cerazette if you have been told by your doctor that you are intolerant to some sugars.

2.8 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 **blood clot** e.g. 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 a sign of a **thrombosis**);
- you have a sudden, severe stomach ache or **jaundice** (you may notice yellowing of the skin, the whites of the eyes, or dark urine, possibly a sign of **liver problems**);
- you feel a lump in your **breast** (possibly a sign of **breast cancer**);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly a sign of an **ectopic pregnancy** - 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 Cerazette

3.1 When and how to take the tablets?
Each strip of Cerazette contains 28 tablets – 4 weeks supply.

- **Take your tablet each day at about the same time. Swallow the tablet whole, with water.**
- Arrows are printed on the front of the strip, between the tablets. The days of the week are printed on the back of the strip. Each day corresponds with one tablet.
- Every time you start a new strip 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 (on the back) with WED.
- Continue to take one tablet every 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.
- You may have some vaginal bleeding during the use of Cerazette, (see section 4 'Possible side effects) but you must continue to take your tablets as normal.
- When a strip is empty, you must start with a new strip of Cerazette on the next day - without interruption and without waiting for a bleed.

3.2 Starting your first pack of Cerazette

- **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 Cerazette tablet. Additional contraceptive precautions are not necessary. If you take your first tablet on days 2-5 of your period use an additional 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 <u>don't have</u> a tablet-, ring- or patch-free break

- Start taking Cerazette 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 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, additional contraceptive precautions are not necessary.**

If <u>you have</u> 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 Cerazette 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 Cerazette 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 have already had sex, check that you are not pregnant before starting Cerazette. Information for breast-feeding women can be found in section 2 'What you need to know before you take Cerazette' in the paragraph 'Pregnancy and breast-feeding'. Your doctor can also advise you.

- **After a miscarriage or an abortion:**

Your doctor will advise you.

3.3 If you forget to take Cerazette

- If you are **less than 12 hours** late:
  - Take the missed tablet as soon as you remember and take the next one at the usual time. Cerazette will still protect you from pregnancy.
- If you are **more than 12 hours** late:
  - If you are more than 12 hours late in taking any tablet, **you may not be completely protected against pregnancy.** The more consecutive tablets you have missed, the higher the risk that you might fall pregnant.
  - Take a tablet as soon as you remember and take the next one at the usual time. This may mean taking two in one day. This is not harmful. (If you have forgotten more than one tablet you don't need to take the earlier missed ones). Continue to take your tablets as usual but you must also use an extra method, such as a condom, for the **next 7 days**.
  - If you are more than 12 hours late taking your tablet and have had sex it is safe to use **emergency contraception;** please consult your pharmacist or doctor.

- If you missed one or more tablets in the **very first week** of starting the tablet and had intercourse in the week before missing the tablets, you may fall pregnant. Ask your doctor for advice.

3.4 If you vomit
If you vomit within 3 - 4 hours after taking your Cerazette tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed. Follow the advice for forgotten tablets in the section above.

3.5 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 young girls, slight vaginal bleeding. For more information ask your doctor for advice.

3.6 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.

4. Possible side effects

Like all medicines, Cerazette can cause side effects, although not everybody gets them.
Tell your doctor if you notice any unwanted effect, especially if severe or persistent.

Serious side effects associated with the use of Cerazette are described in section 2 'What you need to know before you take Cerazette'. Please read this section for additional information on 'Breast cancer' and 'Thrombosis' and consult your doctor at once where appropriate.

You should see your doctor immediately if you experience allergic reactions (hypersensitivity), including swelling of the face, lips, tongue, and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis).

Vaginal bleeding may occur at irregular intervals while using Cerazette. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period. You may need to use tampons or sanitary towels. You may also not have any bleeding at all. Irregular bleeding is not a sign that Cerazette is not working. In general, you need not take any action; just continue to take Cerazette. **If bleeding is heavy or prolonged you should consult your doctor.**

How often are other possible side effects seen?

Common: may affect up to 1 in 10 women
- mood altered, depressed mood, decreased sexual drive (libido)
- headache
- nausea
- acne
- breast pain; irregular or no menstruation
- increased body weight

Uncommon: may affect up to 1 in 100 women
- 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 women
- rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin conditions)

Not known (cannot be estimated from the available data)
- allergic reaction

Apart from these side effects, breast secretion or leakage may occur.

Reporting of side effects
If you get any side effects talk to your doctor, pharmacist or Family Planning Nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cerazette

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

Do not use after the expiry date which is stated on the package. The expiry date is the last day of the month stated.

This medicine does not require any special temperature storage conditions. Store the blister pack in the original sachet in order to protect from light and moisture. Use within 1 month from the date of first opening of the sachet.

The active substance shows an environmental risk to fish.
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 to protect the environment.

6. Contents of the pack and other information

What Cerazette contains
- The active substance is: desogestrel (75 microgram)
- The other ingredients 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 Cerazette looks like and contents of the pack

Each strip of Cerazette contains 28 white round tablets. The tablets are marked KV above 2 on one side and ORGANON* on the other. Cerazette comes in a pack of 1, 3, 6 or 13 strips. Each strip is sealed in a foil sachet. Not all pack sizes may be available.

Marketing Authorisation Holder
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In correspondence please quote packing number.

To listen to or request a copy of this leaflet in **Braille, large print or audio** please call, free of charge: 0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name: Cerazette Reference Number: PL 00025/0562
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