Cerazette® Film-coated tablets, 75 microgram

1. NAME OF THE MEDICINAL PRODUCT

Cerazette ®, 75 microgram film coated tablet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 75 microgram desogestrel.
Excipient: Lactose <65 mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

The tablet is white, round, biconvex and 5 mm in diameter. On one side it is coded KV above 2 and on the reverse side Organon ⁎.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Contraception.

4.2 Posology and method of administration

4.2.1 How to take Cerazette

Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. One tablet is to be taken daily for 28 consecutive days. Each subsequent pack is started immediately after finishing the previous pack.

4.2.2 How to start Cerazette

- *No preceding hormonal contraceptive use [in the past month].*
  Tablet-taking has to start on day 1 of the woman's natural cycle (day 1 is the first day of her menstrual bleeding). Starting on days 2-5 is allowed, but during the first cycle a barrier method is recommended for the first 7 days of tablet-taking.

- *Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring, or transdermal patch).*
  The woman should start with Cerazette preferably on the day after the last active tablet (the last tablet containing the active substances), or on the day of removal of her vaginal ring or patch. In these cases, the use of an additional contraceptive is not necessary.

The woman may also start at the latest on the day following the usual tablet-free, patch-free, ring-free, or placebo tablet interval of her previous combined hormonal contraceptive, but during the first 7 days of tablet-taking an additional barrier method is recommended.

- *Changing from a progestogen-only-method (minipill, injection, implant or from a progestogen-releasing intrauterine system [IUS]).*
  The woman may switch any day from the minipill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due); an additional contraceptive method is not necessary.

- *Following first-trimester abortion.*
  After first-trimester abortion it is recommended to start immediately; an additional contraceptive method is not necessary.

- *Following delivery or second-trimester abortion.*
  For breast-feeding women see Section 4.6.
  The woman should be advised to start at day 21 to 28 after delivery or second-trimester abortion. When starting later, she should be advised to additionally use a barrier method for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of Cerazette use or the woman has to wait for her first menstrual period.

4.2.3 Management of missed tablets

Contraceptive protection may be reduced if more than 36 hours have elapsed between two tablets. If the user is less than 12 hours late in taking any tablet, the missed tablet should be taken as soon as it is remembered and the next tablet should be taken at the usual time. If she is more than 12 hours late, she should follow the same advice but also use an additional method of contraception for the next 7 days. If tablets were missed in the very first week of use and intercourse took place in the week before the tablets were missed, the possibility of a pregnancy should be considered.

4.2.4 Advice in case of gastro-intestinal disturbances

In case of severe gastro-intestinal disturbance, absorption may not be complete and additional contraceptive measures should be taken.

If vomiting occurs within 3-4 hours after tablet-taking, absorption may not be complete. In such an event, the advice concerning missed tablets, as given in Section 4.2.3 is applicable.

4.3 Contraindications

Progestogen-only contraceptives should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during the use of Cerazette, the product should be stopped immediately.

- Hypersensitivity to the active substance or to any of the excipients.
- Known or suspected pregnancy.
- Active venous thromboembolic disorder.

- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.

- Known or suspected sex steroid sensitive malignancies.

- Undiagnosed vaginal bleeding.

4.4 Special warnings and precautions for use

4.4.1 Warnings

If any of the conditions/risk factors mentioned below is present, the benefits of progestogen use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start with Cerazette. In the event of aggravation, exacerbation or first appearance of any of these conditions, the woman should contact her physician. The physician should then decide on whether the use of Cerazette should be discontinued.

- The risk for breast cancer increases in general with increasing age. During use of combined oral contraceptives (COCs) the risk of having breast cancer diagnosed is slightly increased. This increased risk disappears gradually within 10 years after discontinuation of OC use and is not related to the duration of use, but to the age of the woman when using the COC. The expected number of cases diagnosed per 10 000 women who use combined COCs (up to 10 years after stopping) relative to never users over the same period has been calculated for the respective age groups and is presented in the table below

age group	*expected cases combined OC-users*	*expected cases non-users*
16-19 years	4.5	4
20-24 years	17.5	16
25-29 years	48.7	44
30-34 years	110	100
35-39 years	180	160
40-44 years	260	230

The risk in users of progestogen-only contraceptives (POCs), such as Cerazette, is possibly of similar magnitude as that associated with COCs. However, for POCs the evidence is less conclusive. Compared to the risk of getting breast cancer ever in life, the increased risk associated with COCs is low. The cases of breast cancer diagnosed in COC users tend to be less advanced than in those who have not used COCs. The increased risk in COC users may be due to an earlier diagnosis, biological effects of the pill or a combination of both.

- Since a biological effect of progestogens on liver cancer cannot be excluded an individual benefit/risk assessment should be made in women with liver cancer.

- When acute or chronic disturbances of liver function occur the woman should be referred to a specialist for examination and advice.

- If a sustained hypertension develops during the use of Cerazette, or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, discontinuation with the use of Cerazette should be considered.

- Epidemiological investigations have associated the use of combined OCs with an increased incidence of venous thromboembolism (VTE, deep venous thrombosis and pulmonary embolism). Although the clinical relevance of this finding for desogestrel used as a contraceptive in the absence of an estrogenic component is unknown, Cerazette should be discontinued in the event of a thrombosis. Discontinuation of Cerazette should also be considered in case of long-term immobilisation due to surgery or illness. Women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence.

- Although progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using progestogen-only pills. However, diabetic patients should be carefully observed during the first months of use.

- Treatment with Cerazette leads to decreased estradiol serum levels, to a level corresponding with the early follicular phase. It is as yet unknown whether the decrease has any clinically relevant effect on bone mineral density.

- The protection with traditional progestogen-only pills against ectopic pregnancies is not as good as with combined oral contraceptives, which has been associated with the frequent occurrence of ovulations during the use of progestogen-only pills. Despite the fact that Cerazette consistently inhibits ovulation, ectopic pregnancy should be taken into account in the differential diagnosis if the woman gets amenorrhoea or abdominal pain.

- Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Cerazette.

- The following conditions have been reported both during pregnancy and during sex steroid use, but an association with the use of progestogens has not been established: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; (hereditary) angioedema.

- Cerazette contains less than 65 mg lactose and therefore should not be administered to patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption.

4.4.2 Medical examination/consultation

Before prescription, a thorough case history should be taken and a thorough gynaecological examination is recommended to exclude pregnancy. Bleeding disturbances, such as oligomenorrhoea and amenorrhoea should be investigated before prescription. The interval between check-ups depends on the circumstances in each individual case. If the prescribed product may conceivably influence latent or manifest disease (see Section 4.4), the control examinations

should be timed accordingly. Despite the fact that Cerazette is taken regularly, bleeding disturbances may occur. If bleeding is very frequent and irregular, another contraceptive method should be considered. If the symptoms persist, an organic cause should be ruled out. Management of amenorrhoea during treatment depends on whether or not the tablets have been taken in accordance with the instructions and may include a pregnancy test. The treatment should be stopped if a pregnancy occurs.

Women should be advised that Cerazette does not protect against HIV (AIDS) and other sexually transmitted diseases.

4.4.3 Reduced efficacy

The efficacy of Cerazette may be reduced in the event of missed tablets (Section 4.2.3), gastro-intestinal disturbances (Section 4.2.4), or concomitant medications that decrease the plasma concentration of etonogestrel, the active metabolite of desogestrel (Section 4.5.1).

4.4.4 Changes in vaginal bleeding pattern

During the use of a progestogen-only contraceptive, vaginal bleeding may become more frequent or of longer duration in some women, whereas in others bleeding may become incidental or be totally absent. These changes are often a reason for the woman to reject the method or to be non-compliant. Acceptance of bleeding pattern can be improved by offering women who have chosen to use Cerazette careful counselling on this point. Evaluation of vaginal bleeding should be done on an ad hoc basis and may include examination to exclude malignancy or pregnancy.

4.4.5 Follicular development

With all low-dose hormonal contraceptives, follicular development occurs and occasionally the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally, these enlarged follicles disappear spontaneously. Often, they are asymptomatic; in some cases they are associated with mild abdominal pain. They rarely require surgical intervention.

4.5 Interaction with other medicinal products and other forms of interaction

4.5.1 Interactions

Note: The prescribing information of concomitant medications should be consulted to identify potential interactions.

Interactions between oral contraceptives and other medicinal products may lead to breakthrough bleeding and/or contraceptive failure. The following interactions have been reported in the literature (mainly with combined contraceptives but occasionally also with progestogen-only contraceptives).

Hepatic metabolism: Interactions can occur with medicinal or herbal products that induce microsomal enzymes, specifically cytochrome P450 enzymes (CYP), which can result in increased clearance reducing plasma concentrations of sex hormones and may decrease the effectiveness of oral contraceptives, including

Cerazette. These products include phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin, and possibly also oxcarbazepine, rifabutin, topiramate, felbamate, griseofulvin, some HIV protease inhibitors (e.g., ritonavir, nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz), and the herbal remedy St. John's wort.

Enzyme induction can occur after a few days of treatment. Maximum enzyme induction is generally observed within a few weeks. After drug therapy is discontinued, enzyme induction can last for about 28 days.

When co-administered with hormonal contraceptives, many combinations of HIV protease inhibitors (e.g., nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g., nevirapine), and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g., boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins, including etonogestrel, the active metabolite of desogestrel. The net effect of these changes may be clinically relevant in some cases.

Women receiving any of the above mentioned hepatic enzyme-inducing medicinal or herbal products should be advised that the efficacy of Cerazette may be reduced. A barrier contraceptive method should be used in addition to Cerazette during administration of the hepatic enzyme-inducing medicinal product, and for 28 days after discontinuation of the hepatic enzyme-inducing medicinal product.

For women on long-term therapy with enzyme-inducing medicinal products an alternative method of contraception unaffected by enzyme-inducing medicinal products should be considered.

Concomitant administration of strong (e.g., ketoconazole, itraconazole, clarithromycin) or moderate (e.g., fluconazole, diltiazem, erythromycin) CYP3A4 inhibitors may increase the serum concentrations of progestins, including etonogestrel, the active metabolite of desogestrel.

During treatment with medical charcoal, the absorption of the steroid in the tablet may be reduced and thereby the contraceptive efficacy. In such an event, the advice concerning missed tablets, as given in Section 4.2.3 is applicable.

Hormonal contraceptives may interfere with the metabolism of other drugs. Accordingly, plasma and tissue concentrations may either increase (e.g., ciclosporin) or decrease (e.g., lamotrigine).

4.5.2 Laboratory tests

Data obtained with COCs have shown that contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins, e.g., corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. The changes generally remain within the normal range. To what extent this also applies to progestogen-only contraceptives is not known.

4.6 Pregnancy and lactation

Animal studies have shown that very high doses of progestogenic substances may cause masculinisation of female foetuses.

Extensive epidemiological studies have revealed neither an increased risk of birth defects in children born to women who used OCs prior to pregnancy, nor a teratogenic effect when OCs were taken inadvertently during early pregnancy. Pharmacovigilance data collected with various desogestrel-containing combined OCs also do not indicate an increased risk.

Cerazette does not influence the production or the quality (protein, lactose, or fat concentrations) of breast milk. However, a small amounts of etonogestrel are excreted in the breast milk. As a result, 0.01 - 0.05 microgram etonogestrel per kg body weight per day may be ingested by the child (based on an estimated milk ingestion of 150 ml/kg/day).

Limited long-term follow-up data are available on children, whose mothers started using Cerazette during the 4th to 8th week post-partum. They were breast-fed for 7 months and followed up to 1.5 years (n=32) or to 2.5 years (n=14) of age. Evaluation of growth and physical and psychomotor development did not indicate any differences in comparison to nursing infants, whose mother used copper-IUD. Based on the available data Cerazette may be used during lactation. The development and growth of a nursing infant, whose mother uses Cerazette, should, however, be carefully observed.

4.7 Effects on ability to drive and use machines

On the basis of the pharmacodynamic profile, Cerazette is expected to have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most commonly reported undesirable effects in the clinical trials with Cerazette (> 2.5%) were bleeding irregularities, acne, mood changes, breast pain, nausea and weight increase. The undesirable effects mentioned in the table below have been judged, by the investigators, as having an established, probable, or possible link to the treatment.

System Organ Class (MedDRA)*	**Frequency of adverse reactions**		
	Common ≥ 1/100	**Uncommon < 1/100, ≥ 1/1000**	**Rare <1/1000**
Infections and infestations		Vaginal infection	
Psychiatric disorders	Mood altered Libido decreased		
Nervous system disorders	Headache		
Eye disorders		Contact lens intolerance	
Gastrointestinal disorders	Nausea	Vomiting	
Skin and subcutaneous tissue disorders	Acne	Alopecia	Rash, Urticaria, Erythema

			nodosum
Reproductive system and breast disorders	Breast pain, Menstruation irregular, Amenorrhoea	Dysmenorrhoea, Ovarian cyst	
General disorders and administration site condition		Fatigue	
Investigations	Weight increased		

* MedDRA version 9.0;

Breast discharge and, on rare occasions, ectopic pregnancies have been reported with the use of Cerazette during post-marketing surveillance (see Section 4.4). In addition, hypersensitivity reactions (including angioedema and anaphylaxis) have been reported during post-marketing surveillance.

In women using (combined) oral contraceptives a number of (serious) undesirable effects have been reported. These include venous thromboembolic disorders, arterial thromboembolic disorders, hormone-dependent tumours (e.g., breast cancer), and chloasma, some of which are discussed in more detail in Section 4.4.

4.9 Overdose

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are: nausea, vomiting and, in young girls, slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: hormonal contraceptives for systemic use, ATC code: G03A C09.

Cerazette is a progestogen-only pill, which contains the progestogen desogestrel. Like other progestogen-only pills, Cerazette is best suited for use during breast-feeding and for women who may not or do not want to use estrogens. In contrast to traditional progestogen-only pills, the contraceptive effect of Cerazette is achieved primarily by inhibition of ovulation. Other effects include increased viscosity of the cervical mucus.

When studied for 2 cycles, using a definition of ovulation as a progesterone level greater than 16 nmol/L for 5 consecutive days, the ovulation incidence was found to be 1% (1/103) with a 95% confidence interval of 0.02% - 5.29% in the ITT group (user and method failures). Ovulation inhibition was achieved from the first cycle of use. In this study, when Cerazette was discontinued after 2 cycles (56 continuous days), ovulation occurred on average after 17 days (range 7-30 days).

In a comparative efficacy trial (which allowed a maximum time of 3 hours for missed pills) the overall ITT Pearl-Index found for Cerazette was 0.4 (95%

confidence interval 0.09 - 1.20), compared to 1.6 (95% confidence interval 0.42 - 3.96) for 30 μg levonorgestrel.

The Pearl-Index for Cerazette is comparable to the one historically found for combined OCs in the general OC-using population. Treatment with Cerazette leads to decreased estradiol levels, to a level corresponding to the early follicular phase. No clinically relevant effects on carbohydrate metabolism, lipid metabolism, and haemostasis have been observed.

5.2 Pharmacokinetic properties

ABSORPTION
After oral dosing of Cerazette desogestrel (DSG) is rapidly absorbed and converted into its biologically active metabolite etonogestrel (ENG). Under steady-state conditions, peak serum levels are reached 1.8 hours after tablet-intake and the absolute bioavailability of ENG is approximately 70%.

DISTRIBUTION
ENG is 95.5-99% bound to serum proteins, predominantly to albumin and to a lesser extent to SHBG.

METABOLISM
DSG is metabolised via hydroxylation and dehydrogenation to the active metabolite ENG. ENG is metabolised via sulphate and glucuronide conjugation.

ELIMINATION
ENG is eliminated with a mean half-life of approximately 30 hours, with no difference between single and multiple dosing. Steady-state levels in plasma are reached after 4-5 days. The serum clearance after i.v. administration of ENG is approximately 10 l per hour. Excretion of ENG and its metabolites either as free steroid or as conjugates is with urine and faeces (ratio 1.5:1). In lactating women, ENG is excreted in breast milk with a milk/serum ratio of 0.37-0.55. Based on these data and an estimated milk intake of 150 ml/kg/day, 0.01 - 0.05 microgram etonogestrel per kg body weight per day may be ingested by the infant.

5.3 Preclinical safety data

Toxicological studies did not reveal any effects other than those, which can be explained from the hormonal properties of desogestrel.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

TABLET CORE
Silica, colloidal anhydrous; all-*rac*-α-tocopherol; lactose monohydrate; maize starch; povidone; stearic acid.

FILM COATING
Hypromellose; macrogol 400; talc; titanium dioxide (E 171).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store protected from light and moisture below 30 °C

6.5 Nature and contents of container

Blister of 28 tablets each. PVC/Aluminium foil push-through blister (1, 3 or 6 strips per box). Each blister is enveloped in aluminium laminate sachet, packed in a printed cardboard box. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MANUFACTURED BY:

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8. PRODUCT REGISTRATION HOLDER:

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9. DATE OF REVISION:

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