

PRESCRIBING INFORMATION

Cerazette® (See SPC before Prescribing)

Presentation: Three sachets of strips of 28 tablets, each containing 75mcg desogestrel.

Uses: Contraception.

Dosage: One tablet daily at about the same time. There is no pill-free week between strips.

Contraindications: Known or suspected pregnancy, active venous thromboembolic disorder, presence or history of severe hepatic disease with current abnormal liver function tests, known or suspected sex-steroid sensitive malignancies, undiagnosed vaginal bleeding, hypersensitivity to any ingredients.

Precautions and Warnings: Women currently using combined oral contraceptives (COCs) have a slightly increased risk of having breast cancer diagnosed. The risk in users of progestogen only pills is possibly of similar magnitude to COCs. This risk is low compared to the risk of getting breast cancer ever in life. The increased risk in COC users may be due to an earlier diagnosis, biological effects of the pill or a combination of both. Refer to a specialist if acute or chronic disturbances of liver function occur.

Epidemiological studies have associated the use of COCs with an increased incidence of venous thromboembolism (VTE, deep venous thrombosis and pulmonary embolism). It is unclear whether desogestrel used alone carries the same risk. Discontinue in the event of a thrombosis. Consider stopping prior to long term immobilisation due to surgery or illness. Caution patients with a history of thromboembolic disorders. Consider discontinuation if hypertension develops. Benefit/risk assessment should be made in women with liver cancer. Monitor patients with diabetes during the first months of use. Effects on bone density are unknown. 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.

Use in Pregnancy and Lactation: Not recommended during pregnancy. Cerazette does not influence the production or quality of breast milk. Small amounts of the metabolite etonogestrel are excreted with the milk. Limited long term follow-up data (up to 2.5 yrs) on children who were breast-fed do not indicate any differences compared to those whose mother used a copper IUD. However development and growth of the nursing infant should be carefully observed.

Interactions: Interactions may lead to breakthrough bleeding and contraceptive failure. This may be seen with enzyme inducers such as hydantoin, barbiturates, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, rifabutin, felbamate, ritonavir, nelfinavir, griseofulvin and products containing St John's Wort. Reduced absorption of etonogestrel may be seen with medical charcoal. Hormonal contraceptives may interfere with metabolism of other drugs, and therefore increase or decrease their plasma or tissue concentrations.

Adverse Reactions: Refer to SPC for full details. *Common:* irregular bleeding, amenorrhoea, headache, weight gain, breast pain, nausea, acne, mood changes, decreased libido.

Breast discharge may also occur. Other less common and rarely reported side effects are listed on the SPC.

Overdose: No serious effects have been reported. Symptoms may include nausea, vomiting and in young girls, slight vaginal bleeding. Treatment should be symptomatic.

Legal Category: POM

Marketing Authorisation Number : PL 0065/0159

Price: Basic NHS cost 3 x 28 tablets £

Marketing Authorisation Holder : Organon Laboratories Ltd, Cambridge Science Park, Milton Road, Cambridge, CB4 0FL, UK

Please refer to the full SPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events with this product should also be reported to MSD Drug Safety Department on +44 (0)1707-363773.

Date of revision of Prescribing Information: July 2011

Cerazette/PI/UK/07-11/03