CERAZETTE®
(Desogestrel)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (tel: 01992 467272).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Three sachets of strips of 28 tablets, each containing 75 micrograms desogestrel.

USES
Contraception.

DOSAGE AND ADMINISTRATION
One tablet daily, at about the same time. No pill-free week between strips. When no preceding hormonal contraceptive use (in the past month) initiate therapy on day 1 of the woman's natural cycle (first day of 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 therapy. Refer to SmPC for full advice on starting Cerazette; missed tablets; changing from other combined oral contraceptives (COCs) and post-partum.
Special populations:
Hepatic impairment: contra-indicated. Renal impairment: No data Paediatric population: No data in patients under 18 years.

CONTRA-INDICATIONS
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
Women currently using 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 that associated with 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.
A biological effect of progestogens on liver cancer cannot be excluded. Refer to a specialist if acute or chronic disturbances of liver function occur. Benefit/risk assessment should be made in women with liver cancer.
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. Monitor patients with diabetes during the first months of use. Effects on bone density are unknown. Ectopic pregnancy should be considered in woman with amenorrhoea or abdominal pain. Chloasma may occasionally occur. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Cerazette. COCs may affect certain laboratory tests. Whether this applies to POP is unknown. Efficacy may be reduced in the event of missed tablets, gastro-intestinal disturbances, or concomitant medications that decrease the plasma concentration of etonogestrel, the active metabolite of desogestrel. Depressed mood and depression can be associated with hormonal contraceptive use. Depression is a risk factor for suicidal behaviour and suicide. Advise women to contact their physician if they develop mood changes and depressive symptoms.

***Drug Interactions*:** Refer to SmPCs of concomitant medications to identify potential interactions. Microsomal enzyme inducers can increase clearance of sex hormones and may lead to breakthrough bleeding and/or contraceptive failure. Reduced efficacy may be seen with the microsomal enzyme inducers barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, efiravenz, and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate, rifabutin and products containing St John's Wort. Enzyme induction can occur after a few days of treatment, peaking within a few weeks and may last up to 4 weeks after discontinuation. Advise short-term users of enzyme inducers on additonal barrier contraception. Cerazette is not recommended for patients on long-term

therapy with enzyme inducers. Co-administration of contraceptive hormones with some HIV/HCV medications can increase or decrease plasma concentrations of progestins which may be clinically relevant in some cases. Concomitant use of strong or moderate CYP3A4 inhibitors may increase serum concentration of progestins, including etonogestrel, the active metabolite of desogestrel. Hormonal contraceptives may interfere with metabolism of other drugs, and therefore increase or decrease their plasma or tissue concentrations.

***Pregnancy and Lactation*:** Not indicated during pregnancy. Cerazette did not appear to influence breast milk production or quality in clinical trials. However, there have been infrequent postmarketing reports of a decrease in breast milk production. 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. Please refer to SmPC for information on return to fertility.

SIDE EFFECTS
Refer to Summary of Product Characteristics for complete information on side-effects.
Common (≥1/100): irregular bleeding, amenorrhoea, headache, weight gain, breast pain, nausea, acne, mood changes, depressed mood, decreased libido.
Serious (not known): hypersensitivity reactions, including angioedema and anaphylaxis
Other less common and rarely reported side effects are listed in the SmPC.

PACKAGE QUANTITIES AND BASIC NHS COST:
3 x 28 tablets £9.55

Marketing Authorisation Number:
PL 00025/0562

Marketing Authorisation Holder:
Merck Sharp & Dohme Limited,
Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, UK.

Legal Category: POM

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