Femulen®

063/221

Presentation
White tablets engraved "SEARLE" on both sides, containing Ethynodiol Diacetate 500 micrograms.

Uses
Oral Contraception.

Dosage and Administration
Starting on the first day of menstruation, one tablet every day without a break in medication for as long as contraception is required. Additional contraceptive precautions (a sheath or a cap, plus spermicide) should be taken for the first 7 days of the first pack. Tablets should be taken at the same time each day.
Missed tablets: If the women misses one tablet or takes it later than the usual time, contraceptive efficacy may be reduced and additional contraceptive precautions (a sheath or a cap, plus spermicide) should be used until the next period occurs. Women who miss a single tablet should be instructed to take the missed tablet as soon as they remember, even though this may mean taking two tablets on one single day.
The regular tablet for that day should be taken at the usual time. If two or more consecutive tablets are missed Femulen should be discontinued and alternative contraceptive measures should be taken until menstruation occurs and the possibility of pregnancy is excluded.
Vomiting or diarrhoea: Vomiting or diarrhoea may reduce the effectiveness of Femulen, particularly if this should occur at or around the time of ovulation. If an episode of vomiting and/or diarrhoea occurs the woman should be advised to use an additional form of contraception (a sheath or a cap, plus spermicide) until the next menstrual period occurs.

Contraindications
The contraindications for progestogen-only oral contraceptives are: known, suspected, or a past history of breast, genital or hormone dependent cancer; past or present, benign or malignant liver tumours; Dubin-Johnson or Rotor Syndrome; impaired liver function; active liver disease; history during pregnancy of idiopathic jaundice or severe pruritus; disorders of lipid metabolism; undiagnosed abnormal vaginal bleeding or amenorrhoea; known or suspected pregnancy; hypersensitivity to any components.
Combined oestrogen/progestogen preparations have been associated with an increase in the risk of thromboembolic and thrombotic disease. Risk has been reported to be related to both oestrogenic and progestogenic activity. In the absence of long term epidemiological studies with progestogen-only oral contraceptives, it is required that the existence, or history of thrombophlebitis, thromboembolic disorders, cerebral vascular disease, myocardial infarction, angina, coronary artery disease, or a haemoglobinopathy be described as a contraindication to Femulen as it is to oestrogen containing oral contraceptives.

Warnings
Femulen should be discontinued if there is a gradual or sudden, partial or complete loss of vision or any evidence of ocular changes, onset or aggravation of migraine or development of headache of a new kind which is recurrent, persistent or severe, suspicion of thrombosis or infarction, significant rise in blood pressure or if jaundice occurs.
Malignant hepatic tumours have been reported on a rare occasions in long-term users of contraceptives. Benign hepatic tumours have also been associated with oral contraceptive usage. A hepatic tumour should be considered in the differential diagnosis when upper abdominal pain, enlarged liver or signs of intra-abdominal haemorrhage occur. Progestogen-only oral contraceptives may offer less protection against ectopic pregnancy, than against intrauterine pregnancy.

Precautions
Women receiving treatment with Femulen should be kept under regular medical surveillance. Femulen should be discontinued at least 4 weeks before elective surgery or during periods

of prolonged immobilisation. It would be reasonable to resume Femulen two weeks after surgery provided the woman is ambulant. Every woman, however should be considered individually with regard to the nature of the operation, the extent of immobilisation, the presence of additional risk factors and the chance of unwanted conception.
Caution should be exercised where there is the possibility of an interaction between a pre-existing disorder and a known or suspected side effect. The use of Femulen in women suffering from epilepsy, or with a history of migraine or cardiac or renal dysfunction may result in exacerbation of these disorders because of fluid retention. Caution should also be observed in women who wear contact lenses, women with impaired carbohydrate tolerance, depression, gallstones, a past history of liver disease, varicose veins, hypertension, asthma or any disease that is prone to worsen during pregnancy.

Pregnancy
Several reports suggest an association between foetal exposure to female sex hormones, including oral contraceptives, and congenital anomalies.
If a women does not have a menstrual period within 45 days of her last menstrual period, pregnancy should be excluded.

Drug Interactions
Femulen may be rendered less effective and increase incidence of breakthrough bleeding may occur by virtue of drug interaction. At present, drugs suspected to interact in this way include rifampicin, barbiturates, anticonvulsants, and antibiotics.

Nursing Mothers
There is no evidence that progestogen-only oral contraceptives diminish the yield of breast milk. In a study of nursing mothers taking Femulen, the median percentage of norethisterone, the principal metabolite of ethynodiol diacetate given to the mother which was ingested by the infant was 0.02%. No adverse effect of the drug on the infants was noted.

Adverse Effects
Women taking progestogen-only oral contraceptives for the first time may initially experience menstrual irregularity. This may include amenorrhoea, prolonged bleeding and/or spotting and should decrease with time. Clinical investigations with Femulen indicate that side effects are infrequent and tend to decrease as treatment continues. Known or suspected side effects of progestogen-only oral contraceptives include nausea, vomiting, other gastrointestinal symptoms, skin disorders including chloasma, breast and weight changes, ocular changes, headache, migraine, depression, change in libido and appetite, increase in size of uterine myofibromata, and changes in carbohydrate, lipid or vitamin metabolism. Rarely dizziness, hirsutism, haemorrhagic eruption and colitis have been reported in users of progestogen-only oral contraceptives.
The use of oral contraceptives has also been associated with a possible increased incidence of gallbladder disease.
Tests of endocrine, hepatic and thyroid function, as well as coagulation tests may be affected by this preparation.

Overdosage
Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Nausea and vomiting may occur and vaginal withdrawal bleeding may present in pre-pubertal girls. In general, treatment of overdosage is not necessary. However, if thought appropriate, as there is no specific antidote, treatment should be symptomatic.

Pharmaceutical Precautions
Store in a dry place below 30°C (86°F).

Package Quantities
Calender pack of 28 tablets with instructions.

Further Information
Femulen does not necessarily inhibit ovulation but it is believed to discourage implantation of the fertilised ovum by altering the endometrium. Cervical mucus viscosity is also changed which may render the passage of sperm less likely.

SEARLE
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