ESTINOR TABLET 0.75 MG

DESCRIPTION: ESTINOR TABLET 0.75 MG: A round, green tablet, 7 mm in diameter with marking 'DUO 861' & 'flower'.

COMPOSITION: Each tablet contains d-Norgestrel 0.75 mg.

PHARMACODYNAMICS:
Levonorgestrel is progestogen derived from nortestosterone. It is more potent inhibitors of ovulation than norethisterone and have androgenic activity.

PHARMACOKINETICS:
Levonorgestrel is rapidly and almost completely absorbed after administration by mouth and undergoes little first pass hepatic metabolism. It is highly bound to plasma proteins; 42 to 68% to sex hormone binding globulin and 30 to 56% to albumin. The proportion bound to sex hormone binding globulin is higher when it is administered with an oestrogen. Levonorgestrel is metabolised in the liver to sulphate and glucuronide conjugates, which are excreted in the urine and to a lesser extent in the faeces.

INDICATIONS:
Oral contraception. The preparation is an oral contraceptive indicated for females having sexual intercourse occasionally. No more than 4 tablets can be taken monthly at 2 to 4 occasions. To females having sexual intercourse more frequently combined oral contraceptive / or other contraceptive methods are recommended.

RECOMMENDED DOSAGE:
In case of one or once repeated intercourse, one tablet should be taken after the first intercourse. In case intercourse is repeated several times, one tablet should be taken after the first intercourse and one tablet 8 hours later. In this case, 2 tablets are taken at one occasion.
Women who have used enzyme-inducing drugs during the last 4 weeks and need emergency contraception are recommended to use a non-hormonal emergency contraceptive, i.e. Cu-IUD or take a double dose of levonorgestrel (i.e. No more than 4 tablets monthly taken together) for those women unable or unwilling to use Cu-IUD.

ROUTE OF ADMINISTRATION : For oral use

CONTRAINDICATIONS: Disease of the liver and the biliary tract, pregnancy jaundice in the history.

WARNINGS AND PRECAUTIONS:
A thorough personal and family medical history and physical examination should be performed before prescribing oral contraceptives and periodically during their administration. Special attention should be given to blood pressure, breasts, abdomen, and pelvic organs.
Cholestatic jaundice has been reported in users of oral contraceptives. If this occurs, the drug should be discontinued. Patients with a history of jaundice during pregnancy or oral contraceptive-related cholestasis should be carefully observed while taking oral contraceptives.
Steroid hormones may be poorly metabolised in patients with impaired liver function and should be administered with caution to such patients.
Users of oral contraceptives may have disturbances in normal tryptophan metabolism which may result in a relative pyridoxine deficiency. The clinical significance of this is yet to be determined.
Patients should be counselled that this product does not protect against HIV (AIDS) infection or other sexually transmitted disease.
Diarrhoea may increase gastrointestinal motility and reduce hormone absorption.
Not more than 4 tablets are allowed to be taken per month.

INTERACTIONS WITH OTHERS MEDICAMENTS:
Drugs affecting oral contraceptives include rifampicin, phenytoin, carbamazapine, primidone, some protease inhibitors and barbiturates which all have been reported to result in contraceptive failure presumably by enhanced steroid metabolism due to hepatic enzyme induction.
The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, mainly CYP3A4 enzyme inducers. Concomitant administration of efavirenz has been found to reduce plasma levels of levonorgestrel (AUC) by around 50%.
Drugs suspected of having similar capacity to reduce plasma levels of levonorgestrel include barbiturates, phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's wort), rifampicin, ritonavir, and griseofulvin.
For women who have used enzyme-inducing drugs in the past 4 weeks and need emergency contraception, the use of non-hormonal emergency contraception (i.e. a Cu-IUD) should be considered. Taking a double dose of levonorgestrel (i.e. 3mg within 72 hours after the unprotected intercourse) is an option for women who are unable or unwilling to use a Cu-IUD, although this specific combination (a double dose of levonorgestrel during concomitant use of an enzyme inducer) has not been studied.
Breakthrough bleeding has been reported in patients taking oral contraceptives and St. John's wort (hypericum perforatum). St. John's wort may induce hepatic microsomal enzymes which theoretically may result in reduced efficacy of oral contraceptives. If oral contraceptives and St. John's wort are used concomitantly, a non-hormonal back-up method of birth control is recommended.
Increased intermenstrual bleeding and occasional pregnancies have been reported during concomitant administration of oral contraceptives and ampicillin, sulphamethoxypyridazine, chloramphenicol, nitrofurantoin, phenoxymethyl penicillin and neomycin.
The mechanism appears to be reduced enterohepatic circulation of sex steroid due to change in bowel flora. It may be prudent for women to use supplemental forms of contraception during therapy with these antibiotics.

USE IN PREGNANCY AND LACTATION: None available.

SIDE EFFECTS:
Nausea, break-through or withdrawal bleeding may occur 2 - 3 days after taking the tablets, which may be reduced by Rutascorbin administration. In case of more severe bleeding, gynaecological examination is recommended before taking Estinor again.

SYMPTOMS AND TREATMENT OF OVERDOSE:
Overdosage may cause nausea; withdrawal bleeding may occur in females.
Treatment: Normal gastric lavage. Conservative management is recommended. Gastric lavage should be carried out.

STORAGE CONDITIONS: Store below 30°C. Protect from light. Keep out of reach of children. *Jauhkan daripada kanak-kanak.*

PACK SIZES: Blister pack of 1 x 10's tablets/ box

SHELF LIFE: Please refer to outer package.

PRODUCT REGISTRATION HOLDER AND MANUFACTURER:
DUOPHARMA (M) SDN BHD
Lot 2599, Jalan Seruling 59, Kawasan 3,
Taman Klang Jaya, 41200 Klang, Selangor, MALAYSIA.
150000

[Revision Date: 18.04.2019]