EM-Pill

Tablet

Ulipristal Acetate INN 30 mg

COMPOSITION
Each film coated tablet contains Ulipristal Acetate INN 30 mg.

PHARMACOLOGY
EM-Pill is an emergency contraceptive for women. EM-Pill should be used within 120 hours/5 days of unprotected intercourse. It should not be taken as regular birth control pill. Ulipristal Acetate is a Selective Progesterone Receptor Modulator (SPRM) with antagonistic and partial agonistic effects (a progesterone agonist / antagonist) at the progesterone receptor.
EM-Pill (Ulipristal Acetate) is an orally–active synthetic SPRM which acts via high-affinity binding to the human progesterone receptor. The Primary mechanism of action is inhibition or delay of ovulation. Data shows that even when taken immediately before ovulation is scheduled to occur, Ulipristal Acetate is able to postpone follicular rupture in some women.

INDICATION
Ulipristal Acetate is indicated for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

DOSAGE AND ADMINISTRATION
Route of administration : Orally.
One 30 mg EM-Pill tablet must be taken as soon as possible but no later than 120 hours of unprotected intercourse or contraceptive failure, with or without food. If vomiting occurs within 3 hours of intake, then another tablet is needed to be taken. EM-Pill can be taken at any time of menstrual cycle.
OR AS DIRECTED BY THE PHYSICIAN

What is your medicine for and when should this medicine be taken
EM-Pill is an oral emergency contraceptive
What is an emergency contraception?
Emergency contraception is a rescue method which is aimed to prevent fertilization in case of unprotected intercourse.
When can an emergency contraception be used?
This contraception must be used as soon as possible, preferably within 120 hours and no later than 120 hours (5 days) after the unprotected sexual intercourse, particularly;
• if you have had a sexual intercourse whereas either yourself or your partner did not use a contraceptive method;
• if you have forgotten to take consecutive 3 contraceptive pills; (in this case read the information leaflet of your contraceptive pill);
• if your partner's condom has broken, slipped or been improperly removed or if he has forgotten to use it;
• if you have fear that your intrauterine device has been expelled;
• if your vaginal diaphragm or your contraceptive cap has been moved or if you have removed it too early;
• if you are afraid that the method of coitus interruptus has been failed or if supposed to be fertile while using the rhythm method;
• In the event of rape.

CONTRAINDICATION
Ulipristal Acetate is contraindicated in case of hypersensitivity to active substances and in pregnancy. It is not recommended for use in patients with liver disease.

WARNINGS AND PRECAUTIONS
Existing Pregnancy: EM-Pill (Ulipristal Acetate) is not indicated for termination of an existing pregnancy.
Ectopic Pregnancy: A history of ectopic pregnancy is not a contraindication to the use of this emergency contraceptive method.
Repeated use: EM-Pill (Ulipristal Acetate) is for occasional use as an emergency contraceptive. It should not replace a regular method of contraception. Repeated use of Ulipristal Acetate within the same cycle has not been evaluated.
Fertility Following Use: A rapid return of fertility is likely following treatment with EM-Pill (Ulipristal Acetate) for emergency contraception. So, to prevent pregnancy on later episode of sexual intercourse one should use barrier method (ex. condom).
Effect on Menstrual Cycle: After Ulipristal Acetate intake, menses sometimes occur earlier or later than expected by a few days. In clinical trials, cycle length was increased by a mean of 2.5 days but returned to normal in the subsequent cycle. 7% of subjects reported menses occurring more than 7 days earlier than expected, and 19% reported a delay of more than 7 days. If there is a delay in the onset of expected menses beyond 1 week, pregnancy test should be performed. 9% of women studied reported intermenstrual bleeding after use of Ulipristal Acetate.
Hepatic Impairment
No studies have been conducted to evaluate the effect of hepatic disease on the disposition of Ulipristal Acetate.
Renal Impairment
No studies have been conducted to evaluate the effect of renal disease on the disposition of Ulipristal Acetate.

SIDE EFFECTS
Common: Most common side-effects are headache, nausea, abdominal pain, dysmenorrhea, fatigue, dizziness, breast tenderness etc.
Rare: Some rare side-effects are acne, hives, itching & rash.

USE IN PREGNANCY AND LACTATION
Contraindicated in suspected or existing pregnancy. Ulipristal Acetate excretes in breast milk. So breast feeding is not recommended for one week after intake. Extremely limited data available on the health of the fetus/newborn exposed to Ulipristal acetate.

USE IN CHILDREN AND ADOLESCENT
Limited safety and efficacy data available on women under 18 years old.

DRUG INTERACTION
With Medicine: Ulipristal Acetate interacts with the following drugs : Barbiturates, Carbamazepine, Phenobarbital, Rifampicin, Itraconazole, Ketoconazole etc.
With food & others: Cytochrome P450 enzyme inhibitors, cytochrome P450 enzyme inducers, hormonal contraceptions, PPIs, P-glycoprotein substrates progestogens, medicine that affect gastric pH may interact with Ulipristal Acetate.

OVERDOSE
Experience with Ulipristal Acetate overdose is limited. In a clinical study, single dose equivalent to four times Ulipristal Acetate were administered to a limited number of subjects without any adverse reactions.

STORAGE
Store below 30°C, protected from light & moisture.
Keep all medicines out of reach of the children.

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PACKING
Each box contains 1 tablet in a blister strip.

Further information is available on request.

Manufactured by:
The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness