



# Peuli

Ulipristal Acetate  
INN 30 mg  
Tablet

## Composition

**Peuli** 30 mg tablet: Each film coated tablet contains Ulipristal Acetate INN 30 mg.

## Description

**Peuli** (Ulipristal Acetate) tablet is an Emergency Contraceptive (EC) pill that prevents unwanted pregnancy. **Peuli** (Ulipristal Acetate) is a Selective Progesterone Receptor Modulator (SPRM). **Peuli** (Ulipristal Acetate) tablet is supplied for oral administration. The inactive ingredients are- lactose monohydrate, povidone K-30, croscarmellose sodium and magnesium stearate.

## Mechanism of action

**Peuli** (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

One 30 mg **Peuli** 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 needed to be taken. **Peuli** can be taken at any time of menstrual cycle.

## Special warnings and precautions

Existing Pregnancy: **Peuli** (Ulipristal Acetate) is not indicated for termination of an existing pregnancy.

Ectopic Pregnancy: A history of ectopic pregnancy is not a contraindication to use of this emergency contraceptive method.

Repeated Use: **Peuli** (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 menstrual cycle is not recommended, as safety and efficacy of repeat use within the same cycle has not been evaluated.

Fertility Following Use: A rapid return of fertility is likely following treatment with **Peuli** (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.

## Contraindication

Ulipristal Acetate is contraindicated in case of hypersensitivity to active substances and in pregnancy.

## Side-effects

Most common side-effects are headache, nausea, abdominal pain, dysmenorrhea, fatigue, dizziness, breast tenderness etc.

## Drug interaction

Ulipristal Acetate interacts with the following drugs: Barbiturates, Carbamazepine, Phenobarbital, Rifampicin, Itraconazole, Ketoconazole etc.

## 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.

## 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.

## Children and Adolescent

Limited safety and efficacy data available on women under 18 years old.

## Storage

Store in a dry and cool place, protected from sunlight. Do not freeze. Keep out of reach of children.

## Packaging

**Peuli** 30 mg tablet: Each carton contains 1 tablet in blister pack.

Manufactured by :



**Ziska Pharmaceuticals Ltd.**

Kaliakoir, Gazipur, Bangladesh