

Mifepristone USP 200 mg & Misoprostol BP 200 mcg

COMPOSITION

Each carton contains 2 blister strips.

Freston strip: Each strip contains 1 tablet of Mifepristone USP 200 mg.**Miptol strip:** Each strip contains 4 tablets of Misoprostol BP 200 mcg.**PHARMACOLOGY**

Mifepristone: Mifepristone is a synthetic steroid with anti-progestational activity results from competitive interaction with progesterone at progesterone-receptor sites. Based on studies with various oral doses in several animal species the compound inhibits the activity of endogenous or exogenous progesterone and the Menstrual Regulation (MR) results. During pregnancy, the compound sensitizes the myometrium to the contraction-inducing activity of prostaglandins.

Misoprostol: Misoprostol is a synthetic analogue of prostaglandin E₁. It causes myometrial contractions by interacting with specific receptors on myometrial cells. This interaction results in a change in calcium concentration, thereby initiating muscle contraction. By interacting with prostaglandin receptors, Misoprostol causes the cervix to soften and the uterus to contract, resulting in the expulsion of the uterine contents.

INDICATIONS

A-Kit is indicated for menstrual regulation (MR) through 63 days of pregnancy from the first date of the last menstrual period.

DOSAGE AND ADMINISTRATION**Route of Administration :** Oral.

200 mg of **Freston** (Mifepristone) (i.e. 1 tablet) in a single oral dose, followed within 24 to 48 hours by the administration of the prostaglandin analogue **Miptol** (Misoprostol) 800 mcg i.e. 4 tablets (2+2) buccally (between both side of cheek & gum) under strict medical supervision. Wait for 30 minutes. After that, swallow the remaining part of 4 tablets with water.

OR AS DIRECTED BY THE PHYSICIAN.**CONTRAINDICATIONS**

Administration of Mifepristone and Misoprostol combination is contraindicated in patients with any one of the following conditions; History of allergy or known hypersensitivity to Mifepristone, Misoprostol or other prostaglandin, confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy), IUD in place, chronic adrenal failure, haemorrhagic disorders or concurrent anticoagulant therapy, inherited porphyria.

WARNING AND PRECAUTIONS

The combination of Mifepristone & Misoprostol has been prescribed for the patient's specific condition, it may not be the correct treatment for another person, and may be dangerous to the other person if she is or were to become pregnant. Any intrauterine device [IUD] should be removed before treatment with Mifepristone begins. Menstrual Regulation (MR) by surgery is recommended in cases when combination of Mifepristone & Misoprostol fails to cause Menstrual Regulation (MR). Patients who have an ongoing pregnancy at last visit have a risk of fetal malformation resulting from the treatment. Surgical termination / MVA (Manual Vacuum Aspiration) is recommended to manage Menstrual Regulation (MR) / termination of pregnancy failures.

SIDE EFFECTS**Mifepristone:**

Common : The treatment procedure is designed to induce the vaginal bleeding and uterine cramping necessary for Menstrual Regulation (MR). Commonly reported side effects were nausea, vomiting, diarrhea, pelvic pain, fainting, headache, dizziness and asthenia.

Rare : Severe vaginal bleeding, shock and uterine rupture.

Misoprostol:

Common : Gastro-intestinal side effects like diarrhea, abdominal pain, nausea, flatulence, dyspepsia, headache, vomiting, constipation, shivering, hyperthermia, dizziness, pain due to uterine contractions.

Rare : Severe vaginal bleeding, shock and uterine rupture.

USE IN PREGNANCY & LACTATION**Pregnancy:**

Mifepristone and Misoprostol combination is indicated for Menstrual Regulation (MR) (through 63 days pregnancy) and has no other approved indication for use during pregnancy.

Lactation:

Freston (Mifepristone): It is not known whether Mifepristone is excreted through human milk. Many hormones with a similar chemical structure, however, are excreted in breast milk. Since the effects of Mifepristone on infants are unknown, breast-feeding women should consult with their doctor to decide if they should discard their breast milk for a few days following administration of the medications.

Miptol (Misoprostol): Although it is not known whether Misoprostol is excreted through human milk, Misoprostol should not be administered to nursing mothers because the potential excretion of misoprostol acid could cause diarrhea in nursing infants.

USE IN PATIENTS WITH HEPATIC IMPAIRMENT

Patients with hepatic disease should receive a decreased dose of Mifepristone and Misoprostol combination.

USE IN PATIENTS WITH RENAL IMPAIRMENT

No routine dosage adjustment is recommended for Mifepristone and Misoprostol combination in older patients or patients with renal impairment but dosage may need to be reduced if the usual dose is not tolerated.

DRUG INTERACTIONS**Freston (Mifepristone):**

With Medicine : Although specific drug or food interactions with Mifepristone have not been studied, on the basis of this drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin.

With Food and Others : Grapefruit juice may inhibit its metabolism (increasing serum levels of Mifepristone).

Miptol (Misoprostol):

With Medicine : Misoprostol has not been shown to interfere with the beneficial effects of aspirin and signs and symptoms of rheumatoid arthritis. Misoprostol does not exert clinically significant effects on the absorption, blood levels and antiplatelet effects of therapeutic doses of aspirin.

With Food and Others : There is no interaction with food.

OVERDOSE

Mifepristone: No serious adverse reactions were reported in tolerance studies in healthy non pregnant female and healthy male subjects where Mifepristone was administered in single doses greater than threefold of 600 mg for Menstrual Regulation (MR). If a patient ingests a massive overdose, she should be observed closely for signs of adrenal failure.

Misoprostol: Clinical signs that may indicate an overdose are sedation, tremor, convulsions, dyspnea, abdominal pain, diarrhea, fever, palpitations, hypotension or bradycardia. Symptoms should be treated with supportive therapy. However, because Misoprostol is metabolized like a fatty acid, it is unlikely that dialysis would be appropriate treatment for over dosage.

STORAGE

Store below 25° C temperature & dry place, protected from light. Keep all medicines out of reach of children.

PACKING

Each box contains 1 tablet of Freston (Mifepristone) in Alu-Alu blister strip & 4 tablets of Miptol (Misoprostol) in another Alu-Alu blister strip.

* Further information is available on request.



Manufactured by:

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