Femikit™

Mifepristone INN and Misoprostol Dispersion USP Tablets

Description

Mifepristᵀᴹ: Mifepristone is a synthetic anti-progesterone which antagonizes the action of progesterone by competing with its binding to its receptor. Based on extensive studies performed on animals for the oral doses, the compound is found to inhibit endogenous or exogenous progesterone function and Menstrual Regulation (MR) happens. The loss of progesterone activity during pregnancy causes a series of intrauterine and cervical changes that result in termination of pregnancy.

Misoprostᵀᴹ: Misoprostol is a prostaglandin analogue (Prostaglandin E1) that causes uterine contraction completing medical abortion. It binds to particular receptors of myometrial cells to induce heavy contractions in the myometrium, which result in tissue expulsion. Contractions occur due to the modifications in calcium concentrations. Binding of Misoprostol to prostaglandin receptors causes cervical ripening with softening and dilation of the cervix.

Indication

Femikit™ is indicated for early Menstrual Regulation (MR)/termination of pregnancy up to 9 weeks (63 days) of gestation.

Dosage & Administration:

Femikit™ can only be prescribed by qualified medical professionals who are able to assess the gestational age of an embryo and to diagnose ectopic pregnancies.

Day 1 (First visit): Mifepristone administration

One tablet of Mifepristone (200 mg) is taken in a single oral dose under the supervision of a qualified medical professional in a hospital, medical office or clinic.

Day 2 (Second visit): Misoprostol administration

24-48 hours after ingesting of Mifepristone tablet, the patient takes 4 tablets of 200 micrograms (800 micrograms) of Misoprostol buccally or sublingually. Misoprostol tablets can be administered by the patient herself (place two tablets on each side of cheek & gum or under tongue). She should wait for 30 minutes. During the period immediately following the administration of Misoprostol, the patients may need medication for cramps or gastrointestinal symptoms. The patient should be given instructions on what to do if significant discomfort, excessive bleeding or other adverse reactions occur and should be given a phone number to call if she has questions following the administration of Misoprostol.

Day 10 to 14 (Third visit): Post-treatment examination

Patients must return to the clinic, medical office or hospital within 10 to 14 days after the administration of Mifepristone. This visit is very important to confirm by clinical examination or ultra-sonographic scan that a complete termination of pregnancy has occurred. Patients who have an ongoing pregnancy at this 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:

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

Misoprostᵀᴹ: Gastro-intestinal side effects like diarrhea, abdominal pain, nausea, flatulence, dyspepsia, headache, vomiting and constipation, shivering, hyperthermia, dizziness, pain due to uterine contractions, severe vaginal bleeding, shock, pelvic pain, uterine rupture (requiring surgical repair, hysterectomy and/or salpingo-oophorectomy).

Overdose:

Mifepristᵀᴹ: 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 600mg for Menstrual Regulation (MR). If a patient ingests a massive overdose, she should be observed closely for signs of adrenal failure.

Misoprostᵀᴹ: 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. It is not known if misoprostol acid is dialyzable. However, because Misoprostol is metabolized like a fatty acid, it is unlikely that dialysis would be appropriate treatment for overdosage.

Use in Pregnancy and Lactation:

Pregnancy:

Mifepristᵀᴹ: Mifepristone is indicated for use in the termination of pregnancy (through 63 days pregnancy) and has no other approved indication for use during pregnancy. Patients who have an ongoing pregnancy at the last visit have a risk of fetal malformation resulting from the treatment. Surgical termination is recommended to manage Menstrual Regulation (MR) treatment failures.

Lactation:

Mifepristᵀᴹ: It is not known whether Mifepristone is excreted in 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 health care provider to decide if they should discard their breast milk for a few days following administration of the medications.

Misoprostᵀᴹ: Although it is not known whether Misoprostol or Misoprostol acid is excreted in 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

Misoprostᵀᴹ: Patients with hepatic disease should receive a decreased dose.

Use in Patients with Renal Impairment

Misoprostᵀᴹ: No routine dosage adjustment is recommended in older patients or patients with renal impairment but dosage may need to be reduced if the usual dose is not tolerated.

Drug Interaction:

Mifepristᵀᴹ: No interaction studies have been performed. On the basis of this drug's metabolism by CYP3A4, it is possible that Ketoconazole, Itraconazole, Erythromycin and grapefruit juice may inhibit its metabolism (increasing serum levels of mifepristone). Furthermore, Rifampicin, Dexamethasone and certain anticonvulsants (Phenytoin, Phenobarbital, Carbamazepine) may induce Mifepristone metabolism (lowering serum levels of Mifepristone).

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

Precautions:

Mifepristone and Misoprostol combination should not be given to anyone else. Administration must be under the supervision of a qualified physician. The combination of Mifepristone & Misoprostol has been prescribed for the patients' specific condition, it may not be the correct treatment for another patient, and may be dangerous to the other women if she is or were to become pregnant. Any Intra Uterine 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.

Contraindications:

Administration of Mifepristone 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, hemorrhagic disorders or concurrent anticoagulant therapy, inherited porphyria, if a patient does not have adequate access to medical facilities equipped to provide emergency treatment of incomplete process, blood transfusions and emergency resuscitation during the period from the first visit until discharged by the administering physician.

Pharmaceutical Precaution:

Store at or below 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

Packaging:

Femikit™: Each box contains 1 tablet of **Mifepristᵀᴹ** (Mifepristone INN 200 mg/ tablet) & 4 tablets of **Misoprostᵀᴹ** (Misoprostol Dispersion USP equivalent to Misoprost 200 mcg/ Tablet) in a strip.

SK+F

Manufactured for

ESKAYEF PHARMACEUTICALS LTD.

By Popular PHARMACEUTICALS LTD.

Tongi, Gazipur, Bangladesh.

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