



Terminex™

Mifepristone INN 200 mg & Misoprostol BP 200 mcg

Composition

Terminex™: Each box contains two blisters: One blister contains 1 tablet of Mifepristone INN 200 mg (**Mifovent™**) & another blister contains 4 tablets of Misoprostol BP 200 mcg (**Isovent® 200**) each.

Pharmacology

Mifepristone: The anti-progestational activity of Mifepristone 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, results the termination of pregnancy.

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 receptor, Misoprostol causes the cervix to soften and the uterus to contract, resulting in the expulsion of the uterine contents.

Indication

Terminex™ is indicated for the medical termination of intrauterine pregnancy through 9 weeks (63 days) pregnancy.

Dosage & Administration

Treatment with **Terminex™** for the termination of pregnancy requires three times visits to the physician by the patient. Mifepristone may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

Day One: Mifepristone Administration

One 200 mg tablet of Mifepristone is taken in a single oral dose.

Day Two: Misoprostol Administration

The patient will take four 200 µg tablets (800 µg) of Misoprostol buccally within 24-48 hours after ingesting Mifepristone at home. She should wait for 30 minutes.

During the period immediately following the administration of Misoprostol, the patient may need medication for cramps or gastrointestinal symptoms. The patient should be given instructions on what to do if significant discomfort, excessive vaginal bleeding or other adverse reactions occur and should frequently communicate with physician.

Day 14: Post-Treatment Examination

Patients will return to a clinic or hospital under the supervision of the concerned physician for a follow-up visit approximately 14 days after the administration of Mifepristone. This visit is very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred.

Persistence of heavy or moderate vaginal bleeding at this visit, however, could indicate an incomplete abortion.

Patients who have an ongoing pregnancy at this visit have a risk of fetal malformation resulting from the treatment. Surgical termination is recommended to manage medical abortion treatment failures or as directed by the physician.

Adverse Effects

The treatment procedure is designed to induce the vaginal bleeding and uterine cramping necessary to produce an abortion. Nearly all of the women who receive Mifepristone and Misoprostol will report adverse reactions, and many can be expected to report more than one such reaction. Vaginal bleeding and uterine cramping are expected consequences of the action of Mifepristone as used in the treatment procedure. Women also typically experience abdominal pain, including uterine cramping. Other commonly reported side effects were nausea, vomiting and diarrhea.

Overdosage

Mifovent™ (Mifepristone): No serious adverse reactions were reported in tolerance studies in healthy nonpregnant female where Mifepristone is administered in single doses greater than threefold of 600 mg for menstrual regulation. If a patient ingests a massive overdose, she should be observed closely for signs of adrenal failure.

Isovent® 200 (Misoprostol): Clinical signs that may indicate an overdose are sedation, tremor, convulsions, dyspnea, abdominal pain, diarrhoea, 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 should be appropriate treatment for overdosage.

Drug Interaction

Mifepristone: Although specific drug or food interactions with Mifepristone have not been studied, on the basis of the drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin and grapefruit juice may inhibit its metabolism (increasing serum, levels of Mifepristone).

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

Contraindication

Administration of **Terminex™** for the termination of pregnancy is contraindicated in patients with any one of the following conditions:

- 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
- History of allergy to Mifepristone, Misoprostol or other prostaglandin
- Hemorrhagic disorders or concurrent anticoagulant therapy

Use in Pregnancy and Lactation

Terminex™ is indicated for use in the termination of pregnancy (through 63 days' pregnancy) and has no other approved indication for use during pregnancy. 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

Storage

Store in a cool (below 30° C) and dry place, protected from light and moisture. Keep out of the reach of the children.

How Supplied

Terminex™: Each box contains two blisters having one Mifepristone 200 mg Tablet in one blister & four Misoprostol tablets of 200 mcg each in another blister.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.

Pabna, Bangladesh

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