Misotol

Misoprostol USP

COMPOSITION:
Misotol Tablet: Each tablet contains Misoprostol USP 200 microgram.

PHARMACOLOGY:
Misoprostol is extensively absorbed and undergoes rapid de-esterification to its free acid, which is responsible for its clinical activity and unlike the parent compound, is detectable in plasma. Maximum plasma concentrations of Misoprostol acid are diminished when the dose is taken with food and total availability of Misoprostol acid is reduced by use of concomitant antacid. Misoprostol has both antisecretory (inhibiting gastric acid secretion) and (in animals) mucosal protective properties. NSAIDs (nonsteroidal anti-inflammatory drugs) inhibit prostaglandin synthesis and a deficiency of prostaglandins within the gastric mucosa may lead to diminishing bicarbonate and mucus secretion and may contribute to the mucosal damage caused by these agents. Misoprostol can increase bicarbonate and mucus production but in man this has been shown at doses 200 mcg and above that are also antisecretory. It is therefore not possible to tell whether the ability of Misoprostol to reduce the risk of gastric ulcer is the result of its antisecretory effect or its mucosal protective effect or both.

INDICATION:
Antiulcerant Indication: **Misotol** (Misoprostol) is indicated for reducing the risk of NSAID including aspirin induced gastric ulcers in patients at high risk of complications from gastric ulcer, e.g. the elderly and patients with concomitant debilitating disease, as well as patients at high risk of developing gastric ulceration, such as patients with a history of ulcer. **Misotol** (Misoprostol) has not been shown to reduce the risk of duodenal ulcers in patients taking NSAIDs. Misoprostol should be taken for the duration of NSAID therapy. It had no effect, compared to placebo, on gastrointestinal pain or discomfort associated with NSAID use. Gynecological Indication: Labor induction (in unfavorable cervical conditions), In the prevention & treatment of postpartum hemorrhage (PPH)

DOSAGE & ADMINISTRATION:
Antiulcerant dosage & administration: The recommended adult oral dose of **Misotol** (Misoprostol) for reducing the risk of NSAID-induced gastric ulcers is 200 mcg four times daily with food. If this dose cannot be tolerated, a dose of 100 mcg can be used. **Misotol** (Misoprostol) should be taken for the duration of NSAID therapy as prescribed by the physician. **Misotol** (Misoprostol) should be taken with a meal and the last dose of the day should be at bedtime. Renal impairment: Adjustment of the dosing schedule in renally impaired patients is not routinely needed but dosage can be reduced if the 200 mcg dose is not tolerated.
Gynecological dosage & administration:
- Induction of labor: 25 mcg vaginally 6 hourly or 50 mcg orally 4 hourly.
- Postpartum hemorrhage (PPH) prophylaxis: 400 mcg to 600 mcg orally or rectally immediately following delivery of the child.
- Postpartum hemorrhage (PPH) treatment: 1000 mcg rectally or 200 mcg orally with 400 mcg sublingually

ADVERSE EFFECT:
Gastrointestinal: GIT disorders had the highest reported incidence of adverse events for patients receiving this preparation can cause more abdominal pain, diarrhea and other GIT symptoms. The incidence of diarrhea can be minimized by administering it with food and by avoiding coadministration with magnesium-containing antacids. Gynecological: Gynecological disorders such as spotting, cramps, hypermenorrhea, menstrual disorder and dysmenorrhea have been reported. Postmenopausal vaginal bleeding may be related to Misoprostol administration. Elderly: Overall, there were no significant differences in the safety profile in patients 65 years of age or older compared with younger patients.

CONTRAINDICATION:
Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs). Misoprostol should not be taken by anyone with a history of allergy to prostaglandins.

PRECAUTION & WARNING:
Precaution should be taken in conditions where hypertension might precipitate severe complications (e.g. cerebrovascular and cardiovascular disease).

DRUG INTERACTION:
There is no evidence of clinically significant interaction between Misoprostol and cardiac, pulmonary and CNS drugs and NSAIDs. Bioavailability of Misoprostol is decreased with high doses of antacid.

USE IN PREGNANCY AND LACTATION:
Because of the abortifacient property of the Misoprostol component, it is contraindicated in women who are pregnant. It should not be used in women of childbearing potential unless the patient requires nonsteroidal anti-inflammatory drug (NSAID) therapy and is at high risk of developing gastric or duodenal ulceration or for developing complications from gastric or duodenal ulcers associated with the use of the NSAID.
In such patients, it may be prescribed if the patient:
- has a negative serum pregnancy test within 2 weeks prior to beginning therapy.
- is capable of complying with effective contraceptive measures.
- has received both oral and written warnings of the hazards of Misoprostol, the risk of possible contraception failure and the danger to other women of childbearing potential should the drug be taken by mistake.
- will begin it only on the second or third day of the next normal menstrual period.

Excretion of the active metabolite (Misoprostol acid) into milk is possible but has not been studied. Because of the potential for serious adverse reactions in nursing infants, it is not recommended for use by nursing mothers.

STORAGE:
Store in a cool and dry place, protected from light and moisture. Keep out of the reach of the children.

HOW SUPPLIED:
Misotol Tablet: Each box contains 2 x 10's Tablets in Alu-Alu blister pack.

Manufactured by:
ZISKA PHARMA
Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh