Miptol

Tablet

Misoprostol BP 200 mcg

COMPOSITION
Each tablet contains Misoprostol BP 200 mcg.

PHARMACOLOGY
Misoprostol a synthetic prostaglandin E_1 analogue that has both antisecretory (inhibiting gastric acid secretion) and (in animals) mucosal protective properties. NSAIDs 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, its mucosal protective effect or both.

INDICATIONS
Gynecological indications
- In the prevention and treatment of Postpartum Hemorrhage (PPH).
- Labor induction (In unfavorable cervical conditions).
- Incomplete abortion and miscarriage.

Antiulcerant Indication
Miptol (Misoprostol) is indicated for reducing the risk of NSAID induced gastric ulcers in patients at high risk of complications from gastric ulcer.

DOSAGE AND ADMINISTRATION
Route of Administration : Oral, Sublingual, Vaginal.
Gynecological dosage & administration
Induction of Labor
25 mcg vaginally. Repeat after every 6 hours if necessary until the maximum dosage of 200 mcg total misoprostol is reached. Vaginal route is well established. Misoprostol has also been given orally 50 mcg 4 hourly. But this route is less established. However, in both cases uterus contractions and fetal heart rate should be monitored properly.
Postpartum Hemorrhage (PPH) prophylaxis
600 mcg orally immediately following delivery of the child after confirming that there is no mutiple pregnancy.
Postpartum Hemorrhage (PPH) treatment
1000 mcg rectally or 200 mcg orally with 400 mcg sublingually or 600 mcg orally.
Incomplete abortion (4-12 weeks gestation): 600 mcg orally as a single dose.
Antiulcerant dosage & administration
The recommended adult oral dose of Miptol (Misoprostol) for 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. Miptol (Misoprostol) should be taken for the duration of NSAID therapy as prescribed by the physician. Miptol (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 dose can be reduced if the 200 mcg dose is not tolerated.
OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATION
Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by Non Steroidal Anti Inflammatory Drugs (NSAIDs). Misoprostol should not be taken by anyone with a history of allergy to prostaglandins.

WARNING & PRECAUTIONS
Precaution should be taken in conditions where hypertension might precipitate severe complications. (e.g. cerebrovascular and cardiovascular disease)
- This pack should be given to the mother after 32 weeks of pregnancy.
- This drug cannot be used before delivery of the body of by the pregnant woman.

SIDE EFFECTS
Common :
Gastrointestinal : GI disorders had the highest reported incidence of adverse events for patients receiving this preparation. It can cause more abdominal pain, diarrhea and other GI symptoms. The incidence of diarrhea can be minimized by administering it with food and by avoiding co-administration 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 ulcer patients 65 years of age or older compared with younger patients.
Rare :
Severe vaginal bleeding, shock and uterine rupture.

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 non steroidal 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 had 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.

DRUG INTERACTION
With Medicine : 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.
With food and others : There is no interaction with food.

STORAGE
Store below 25^0 C temperature & dry place, protected from light.
Keep all medicines out of reach of children.

PACKING
Each Box contains 3x10 tablets in Alu-Alu blister strips.

Further information is available on request.

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness