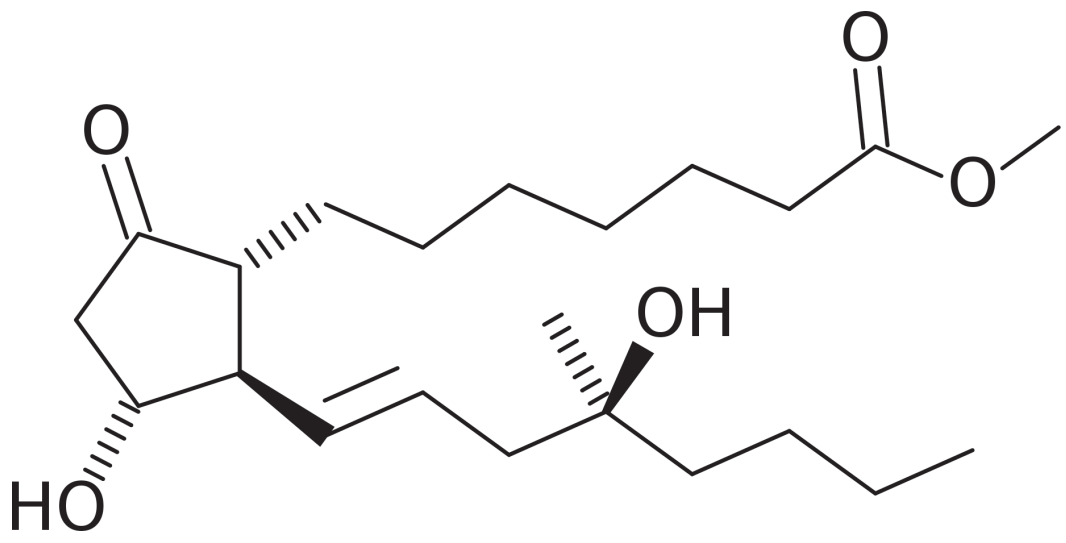
Mite™ 200mcg
(MISOPROSTOL) Tablets

مائٹ ۲۰۰ مائیکروگرام
(میزوپروسٹول) ٹیبلٹس

DESCRIPTION:
MITE (MISOPROSTOL) oral tablets contain misoprostol, a synthetic prostaglandin E1 analog.

Misoprostol



Composition:
Each tablet contains: Misoprostol U.S.P. 200mcg
Genix Specification

CLINICAL PHARMACOLOGY:
Mechanism of Action: Misoprostol inhibits gastric acid secretion by a direct action on the parietal cells through binding to the prostaglandin receptor. The activity of this receptor is mediated by G proteins which normally activate adenylate cyclase. The indirect inhibition of adenylate cyclase by Misoprostol may be dependent on guanosine-5'-triphosphate (GTP). The significant cytoprotective actions of misoprostol are related to several mechanisms

Pharmacokinetics: 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.

Absorption: Misoprostol is rapidly absorbed after oral administration with a Tmax of misoprostol acid of 12 ± 3 minutes and a terminal half-life of 20-40 minutes.

Mean ± SD	c_{max}(pg/ml)	AUC (0-4) (pg.hr/ml)	T_{max}(min)
Fasting	811 ± 317	417 ± 135	14 ± 8
With Antacid	689 ± 315	349 ± 108*	20 ± 14
With High Fat Breakfast	303 ± 176*	373 ± 111	64 ± 79*

*Comparisions with fasting results statisically significant, p>0.05

Distribution: Misoprostol high variability of plasma levels between and within studies. Mean plasma levels after single oral doses show a linear relationship with dose over the range of 200-400 mcg. Serum protein binding less than 90%, concentrationindependent in the therapeutic range.

Metabolism: Misoprostol Undergoes rapid de-esterification to its free acid which is clinically active (misoprostol acid). Misoprostol acid further metabolised by oxidation, primarily in the liver.

Excretion: After oral administration of radiolabeled misoprostol, about 80% of detected radioactivity appears in urine. Plasma elimination half-life reported to be between 20 and 40 minutes. 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 studies between misoprostol and several nonsteroidal anti-inflammatory drugs showed no effect on the kinetics of ibuprofen or diclofenac, and a 20% decrease in aspirin AUC, not thought to be clinically significant.

Pharmacodynamics: Misoprostol 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:

MITE (misoprostol) is indicated for reducing the risk of NSAID (nonsteroidal anti-inflammatory drugs including aspirin)-induced gastric ulcers in patients at high risk of complications from gastric ulcer, eg,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.

DOSAGE AND ADMINISTRATION:

The recommended adult oral dose of MITE (misoprostol) for reducing the risk of NSAID-induced gastric ulcers is 200mcg four times daily with food. If this dose cannot be tolerated, a dose of 100 mcg can be used.
Misoprostol should be taken for the duration of NSAID therapy as prescribed by the physician. Misoprostol should be taken with a meal, and the last dose of the day should be at bedtime.

ADVERSE EFFECTS:

The following have been reported as adverse events in subjects receiving Misoprostol:

Gastrointestinal: In subjects receiving Misoprostol 400 or 800 mcg daily in clinical trials, the most frequent gastrointestinal adverse events were diarrhea and abdominal pain. The incidence of diarrhea 14–40% and in all studies (over 5,000 patients) averaged 13%. Abdominal pain occurred in 13–20% of patients in NSAID trials and about 7% in all studies, but there was no consistent difference from placebo.

Gynecological: Women who received Misoprostol during clinical trials reported the following gynecological disorders: spotting (0.7%), cramps (0.6%), hypermenorrhea (0.5%), menstrual disorder (0.3%) and dysmenorrhea (0.1%).

PRECAUTIONS:

Caution should be employed when administering Misoprostol to patients with pre-existing cardiovascular disease.
Women of childbearing potential using Misoprostol to decrease the risk of NSAID-induced ulcers should be told that they must not be pregnant when Misoprostol therapy is initiated, and that they must use an effective contraception method while taking Misoprostol.

Pregnancy: Pregnancy Category X

Nursing mothers: Misoprostol is rapidly metabolized in the mother to misoprostol acid, which is biologically active and is excreted in breast milk. There are no published reports of adverse effects of misoprostol in breast-feeding infants of mothers taking misoprostol. Caution should be exercised when misoprostol is administered to a nursing woman.

Pediatric use: Safety and effectiveness of MITE (misoprostol) in pediatric patients have not been established.

OVERDOSE:

The toxic dose of Misoprostol in humans has not been determined. Cumulative total daily doses of 1600 mcg have been tolerated, with only symptoms of gastrointestinal discomfort being reported. 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.

WARNINGS:

Misoprostol administration to women who are pregnant can cause abortion, premature birth, or birth defects. uterine rupture has been reported when misoprostol was administered in pregnant women to induce labor or to induce abortion beyond the eighth week of pregnancy. Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDS). Patients must be advised of the abortifacient property and warned not to give the drug to others. Misoprostol should not be used for reducing the risk of NSAID-induced ulcers in women of childbearing potential unless the patient is at high risk of complications from gastric ulcers associated with use of the NSAID, or is at high risk of developing gastric ulceration. In such patients, misoprostol 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 misoprostol only on the second or third day of the next normal menstrual period.

CONTRAINDICATIONS:

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.

INSTRUCTIONS:

Dosage as directed by the physician.
Store below 30°C.
Protect from heat, light & moisture.
Keep all medicines out of the reach of children.

PRESENTATION:

Mite 200mcg tablets are available in Alu-Alu blister pack of 1x10's.

ہدایات:
خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔
روشنی، گرمی اور نمی سے محفوظ رکھیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

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