

TECMISO Tablets

ٹیکمائزول گولیاں

(Ph. Int. مائزوپروسٹول)

(Misoprostol Tablets Ph. Int.) 200mcg

۲۰۰مائیکروگرام

COMPOSITION:

Each tablet contains:

Misoprostol Dispersion Ph. Int. equivalent to Misoprostol ... 200mcg.

[Ph. Int. Specs.]

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 concentration of Misoprostol acid is diminished when the dose is taken with food and total availability of Misoprostol acid is reduced by use of concomitant antacid. Misoprostol has both anti-secretory (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 200mcg and above that are also anti-secretory. It is therefore not possible to tell whether the ability of Misoprostol to reduce the risk of gastric ulcer is the result of its anti-secretory effect, its mucosal protective effect, or both.

MODE OF ACTION:

Misoprostol belongs to a group of hormones called prostaglandins which can cause uterine contractions and opening (ripening) of the cervix. Although prostaglandins, are highly effective, their efficacy depends on number of prostaglandins receptors in the uterus and this varies according to whether the women is pregnant and of what stage of pregnancy she is. At the end of pregnancy there are many receptors and a small dose of Misoprostol leads to strong contractions.

INDICATIONS:

Gynecological Indication:

In the prevention & treatment of Post Partum Hemorrhage (PPH).

Anti-Ulcerant Indication:

Misoprostol is indicated for reducing the risk of NSAID (nonsteroidal anti-inflammatory drugs, including aspirin) induced gastric ulcers in patients with high risk of complications from gastric ulcer, e.g., the elderly and patient with concomitant debilitating disease, as well as patients at high risk of developing gastric ulceration, such as patients with history of ulcer and arthritic patients at risk, whilst continuing their NSAID therapy. Misoprostol has not been shown to reduce the risk of duodenal ulcer in patient taking NSAID. Misoprostol should be taken for the duration of NSAID therapy. It had no effect, compared to placebo, on gastrointestinal pain and discomfort associated with NSAID use.

CONTRA-INDICATIONS:

Misoprostol is contra-indicated: In women who are pregnant, or in whom pregnancy has not been excluded, or who are planning a pregnancy as Misoprostol increases uterine tone and contractions in pregnancy which may cause partial or complete expulsion of the products of conception. Use in pregnancy has been associated with birth defects. In patients with a known hypersensitivity to Misoprostol or to any other component of the product, or to other prostaglandins.

DOSAGE AND ADMINISTRATION:

Gynecological Dosage & Administration:

Post Partum Hemorrhage (PPH) Prophylaxis:

The recommended adult oral dose of Misoprostol is 2-3 tablets of 200mcg.

Post Partum Hemorrhage (PPH) Treatment:

The oral recommended dose is between 200mcg-800mcg.

Do not repeat for 2 hours.

Anti-Ulcerant Dosage & Administration:

The recommended adult oral dose of 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 100mcg can be used.

Rev: 03-21/3

Misoprostol should be taken for the duration of NSAID therapy as prescribed by the physician. Misoprostol should be taken with 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 200mcg dose is not tolerated.

ADVERSE EFFECT:

Gastro-intestinal:

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. Post-menopausal vaginal bleeding may be related to Misoprostol administration.

Elderly:

Overall, there were no significant differences in the safety profile in patients 65 year of age or older compare with younger patients.

PRECAUTION AND 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 contra- indicated in women who are pregnant. It should not be used in women of child bearing potential unless the patient requires nonsteroidat anti-inflammatory drug (NSAIDs) therapy and it is at high risk of developing complications from gastric or duodenal ulcers associated with the use of the NSAIDs.

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 warning of hazards of Misoprostol the risk of possible contraception failure, and the danger of other women of child bearing 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 reaction in nursing infants.
- It is not recommended for use by nursing mothers.

INSTRUCTIONS: Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of children.

PRESENTATION:

TECMISO (Misoprostol) 200mcg Tablets is available in a pack of 1 x 10's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔



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