

preparation. It can cause more abdominal pain, diarrhea and other GI symptoms. The incidence of diarrhoea can be minimized by administering it with food and by avoiding co-administration with magnesium containing antacids.

Gynaecological:

Gynaecological disorders such as spotting, cramps, hypermenorrhea, menstrual disorder and diarrhoea have been reported. Postmenopausal vaginal bleeding may be related to Misoprostol administration.

Elderly:

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

CONTRAINDICATION:

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

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 drug 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 child bearing potential unless the patient requires non steroidal 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 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.

STORAGE:

Store below 30°C.
Protect from light & moisture.
Keep out of the reach of children.

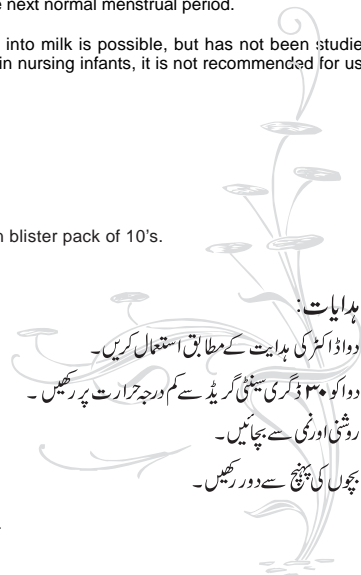
HOW SUPPLIED:

Cytotol (Misoprostol) 200mcg tablets are available in blister pack of 10's.

 **Saffron**

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ہدایات:

دوا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰°C سے کم درجہ حرارت پر رکھیں۔

رڈنی اور نی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

Cytotol 200mcg
(Misoprostol)

سائٹوٹول ۲۰۰ میگروگرام
(میزوپروسٹول)

COMPOSITION: Each tablet contains Misoprostol 200mcg.

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 are diminished when the does 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 deficiency of prostaglandins with in 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:

Cytotol (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 at 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:

Gynaecological Indication:

- In the prevention & treatment of Post Partum Hemorrhage (PPH)
- Labor Induction (in Unfavourable cervical conditions)

Antiulcerant Indication:

Cytotol (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. Cytotol (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.

DOSAGE AND ADMINISTRATION:

Gynecological Dosage & Administration:

Post Partum Hemorrhage (PPH) Prophylaxis: According to United States Pharmacopeia (USP); 400mcg to 600mcg orally or rectally immediately, following delivery of the child.

Post Partum Hemorrhage (PPH) Treatment: According to clinical studies: 600mcg orally or, 1000mcg rectally or, 200mcg orally with 400mcg sublingually. If Cytotol has been given as prophylaxis for PPH, a repeat dose of Cytotol should not be give unless, at least two hours have elapsed since the first dose.

Induction of Labor: According to clinical studies: 25mcg vaginally 4 hourly (max. x 6) or, 50mcg orally 4 hourly (max. x 6) According to World Health Organization (WHO) : 25mcg vaginally 4 hourly (max. x 6).

Anti Ulcerant Dosage & Administration:

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

Gastrointestinal:

GI disorders had the highest reported incidence of adverse events for patients receiving this