Misotac Tablets

SIGMA PHARMACEUTICAL INDUSTRIES

Generic name:
Misoprostol

Composition:
Each tablet contains:
Active ingredient: Misoprostol 200 mcg
Inactive ingredients: Croscarmellose sodium, Aerosil 200, microcrystalline cellulose.

Pharmaceutical form:
Tablets

Pharmacological action
Misotac is an analogue of naturally occurring prostaglandin E1 which promotes peptic ulcer healing and symptomatic relief.
Misotac protects the gastroduodenal mucosa by inhibiting basal, stimulated and nocturnal acid secretion and by reducing the volume of gastric secretions, the proteolytic activity of the gastric fluid, and increasing bicarbonate and mucus secretion.

Pharmacokinetics:
Misotac is rapidly absorbed following oral administration, with peak plasma levels of the active metabolite (misoprostol acid) occurring after about 30 minutes. The plasma elimination half-life of misoprostol acid is 20-40 minutes. No accumulation of misoprostol acid in plasma occurs after repeated dosing of 400 micrograms twice daily.

Indications:
Misotac is indicated for the healing of duodenal ulcer and gastric ulcer including those induced by non steroidal anti-inflammatory drugs (NSAID) in arthritic patients at risk, whilst continuing their NSAID therapy. In addition, Misotac can be used for the prophylaxis of NSAID-induced ulcers.

Dosage and administration:
Use in hospitals only and under medical supervision and not by community pharmacies.
Adults
Healing of duodenal ulcer, gastric ulcer and NSAID-induced peptic ulcer: 800 micrograms daily in two or four divided doses taken with breakfast and / or each main meal and at bed time.
Treatment should be given initially for at least 4 weeks even if symptomatic relief has been achieved sooner. In most patients ulcers will be healed in 4 weeks but treatment may be continued for up to 8 weeks if required. If the ulcer relapses further treatment courses may be given.
Prophylaxis of NSAID-induced peptic ulcer: 200 micrograms twice daily, three times daily or four times daily. Treatment can be continued as required. Dosage should be individualized according to the clinical condition of each patient.
Elderly
The usual dosage may be used.
Renal impairment: Available evidence indicates that no adjustment of dosage is necessary in patients with renal impairment.
Hepatic impairment: **Misotac** is metabolized by fatty acid oxidizing systems present in organs throughout the body. Its metabolism and plasma levels are therefore unlikely to be affected markedly in patients with hepatic impairment.
Children
Use of **Misotac** in children has not yet been evaluated in the treatment of peptic ulceration or NSAID-induced peptic ulcer disease.

Contraindications:
Misotac is contraindicated in patients with a known allergy to prostaglandins.

Side effects:
Gastrointestinal system: Diarrhea has been reported and is occasionally severe and prolonged and may require withdrawal of the drug. It can be minimized by using single doses not exceeding 200 micrograms with food and by avoiding the use of predominantly magnesium containing antacids when an antacid is required. Abdominal pain with or without associated dyspepsia or diarrhea can follow misoprostol therapy.
Other gastrointestinal adverse effects reported include dyspepsia, flatulence, nausea and vomiting.
Female reproductive system: Menorrhagia, vaginal bleeding and intermenstrual bleeding have been reported in pre-and post-menopausal women.
Other side effects: Skin rashes have been reported. Dizziness has been infrequently reported.
The pattern of side effects associated with **Misotac** is similar when an NSAID is given concomitantly.
A number of side effects have been reported in clinical studies or in the literature following use of misoprostol for non-approved indications. These include: Abnormal uterine contractions, uterine haemorrhage, retained placenta, amniotic fluid embolism, incomplete abortion and premature birth.

Drug interactions:
Misotac is predominantly metabolized via fatty acid oxidizing systems and has shown no adverse effect on the hepatic microsomal mixed function oxidase (P450) enzyme system. In specific studies no clinically significant pharmacokinetic interaction has been demonstrated with antipyrine, diazepam and propranolol. In extensive clinical studies no drug interactions have been attributed to **Misotac**. Additional evidence shows no clinically important pharmacokinetic or pharmacodynamic interaction with nonsteroidal anti-inflammatory drugs including aspirin, diclofenac and ibuprofen.

Pregnancy and lactation:
Pregnancy: **Misotac** is contraindicated in pregnant women and in women planning a pregnancy as it 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.
Lactation: It is not known if the active metabolite of **Misotac** is excreted in breast milk; therefore **Misotac** should not be administered during breast feeding.

Precautions and warnings:
This product should be dispensed by hospitals and under physician supervision, and not by community pharmacies.
- Use in pre-menopausal women: **Misotac** should not be used in pre-menopausal women unless the patient requires nonsteroidal anti-inflammatory (NSAID) therapy and is at high risk of complications from NSAID-induced ulceration. In such patients it is advised that **Misotac** should only be used if the patient:
• takes effective contraceptive measures
• has been advised of the risks of taking **Misotac** if pregnant
If pregnancy is suspected the product should be discontinued.
- The results of clinical studies indicate that **Misotac** does not produce hypotension at dosages effective in promoting the healing of gastric and duodenal ulcers. Nevertheless, **Misotac** should be used with caution in the presence of disease states where hypotension might precipitate severe complications, e.g., cerebrovascular disease, coronary artery disease or severe peripheral vascular disease including hypertension.
- There is no evidence that **Misotac** has adverse effects on glucose metabolism in human volunteers or patients with diabetes mellitus.

Patient instructions:
Keep out of reach of children.

Package and storage:
A box containing one or two (Al / Al) strips each of 10 tablets
Store in dry place at temperature not exceeding 30°C.

Produced by: **SIGMA** Pharmaceutical Industries - Egypt - S.A.E.