

Misopa®

Misoprostol
Tablet

Description

Misopa® (Misoprostol) is a synthetic prostaglandin E1 analogue that has gastric antisecretory and mucosal protective properties. The antisecretory activity of misoprostol is mediated through a class of high affinity E-type prostaglandin receptors on the surface of gastric parietal cells. Misoprostol achieves cytoprotection by stimulation of gastric mucus secretion, duodenal bicarbonate secretion and gastric mucosal blood flow.

Indications

Misopa® tablet is indicated for reducing the risk of NSAIDs (nonsteroidal anti-inflammatory drugs), including aspirin-induced gastric ulcers in patients at high risk of complications from gastric ulcer, e.g., 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 Misoprostol for reducing 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. Misoprostol should be taken for the duration of NSAIDs therapy as prescribed by the physician. 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 dosage can be reduced if the 200-mcg dose is not tolerated.

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.

Adverse Reactions

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 patients 65 years of age or older compared with younger patients.

Warning & Precautions

Precaution should be taken in conditions where hypertension 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.

Pharmaceutical Precautions

Store in cool and dry place, away from children.

Commercial Pack

Misopa®200 tablet : Box containing 3×10's Alu-Alu form packs. Each tablet contains Misoprostol BP 200 microgram.

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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