REBAMIPIDE

MUCOPROTEC

100 mg Film-Coated Tablet

Peptic Ulcer and Gastro-oesophageal Reflux Disease

FORMULATION :
Each Film-Coated tablet contains:
Rebamipide ····· 100 mg

DESCRIPTION :
White, round, film-coated, tablet marked with “RE” on one side and “KD” on the other side of the tablet.

PHARMACOKINETICS :
Rebamipide improves the speed and quality of peptic ulcer healing whether given alone or in combination with proton pump inhibitors or H_2 receptor antagonists and has been shown to reduce the rate of recurrence of gastric ulcers, regardless of the status of Helicobacter pylori infection. The ability of rebamipide to effect healing of acute gastritis and gastric ulcers is presumed to be due to its gastric cytoprotective action which results from its ability to increase gastric mucosal endogenous prostaglandin production and to scavenge hydroxyl radicals. Rebamipide has also been shown to be as effective as misoprostol in preventing nonsteroidal anti-inflammatory drug (NSAID)-induced gastric mucosal injury perhaps by preventing the decrease in gastric mucosal blood flow seen in patients taking NSAIDs. In addition, studies done in animals and human subjects indicate that one of the principal gastric defense mechanisms afforded by Rebamipide is through an increased gastric mucus secretion, probably resulting from the stimulation of endogenous prostaglandin production in the gastric mucosa. Futhermore, Rebamipide suppresses gastric mucosal inflammation which is thought to be related to inhibition of superoxide anion production from neutrophils, scavenging of hydroxyl radicals and inhibition of interleukin 8 production.
Rebamipide administered orally as 100 mg tablets reaches peak plasma concentrations (T_{max}) in 2.4 hours and has an elimination half-life ($T_{½}$) of 1.94 hours. Oral administration of Rebamipide after a meal delayed its absorption but did not have any effect on its bioavailability. Rebamipide is highly protein bound with plasma protein binding of around 98%. Rebamipide is excreted mainly as the unchanged drug in the urine after oral administration. Administration of single doses of Rebamipide 100 mg tablets in patients with renal insufficiency resulted in higher plasma concentrations and longer elimination half-lives compared to normal healthy subjects. Repeated oral administrations of Rebamipide in steady-state conditions among renal failure patients undergoing dialysis resulted in plasma concentrations that were almost similar to that observed with single oral administrations indicating that the drug does not accumulate.

INDICATION :
For the treatment of gastric mucosal lesions (erosion, bleeding, redness and edema) in acute gastritis and exacerbation of chronic gastritis; For the prevention of NSAID-induced gastropathy; For the treatment of gastric ulcers.

DOSAGE AND ADMINISTRATION :
The usual adult dose is 100 mg tablet, one tablet three times a day. Or as prescribed by the physician.

ADVERSE DRUG REACTIONS :
The adverse events noted in placebo-controlled trials were rare occurring in less than 1% of the patients and were no more frequent compared to those observed among patients given placebo.

Central Nervous System – dizziness, drowsiness.
Gastrointestinal – ALT and AST elevation, hyperbilirubinemia, dry mouth, constipation, diarrhea, abdominal distention, nausea, vomiting, eructation.
Renal – edema, BUN elevation.
Endocrine – gynecomastia, induction of lactation, menstrual disorders, hot flushes.
Hematologic – leucopenia, leukocytosis, thrombocytopenia.
Skin/hypersensitivity – rash, urticaria, eczema.

SPECIAL WARNINGS AND PRECAUTIONS :
Reproductive and developmental studies conducted in rats showed no toxic effects on reproductive outcome and fetal development, however since the safety of Rebamipide in human pregnancy has not been established, it should not be used in pregnant women or among those who are suspected to be pregnant except in clinical circumstances where there is no appropriate alternative therapy. The safety of Rebamipide in pediatric patients has also not been established and therefore should not be used in these patients. In animal studies, Rebamipide has been reported to be excreted in breast milk and should not be administered to nursing mothers until its safety among breast-feeding infants has been clarified. The adverse events and its frequency of occurrence among the elderly are no different from those that are observed in younger patients but because of the changes in physiologic functions ob-

served in elderly patients, caution should still be taken when administering the drug in this population group with especial attention given to the occurrence of gastrointestinal adverse events.

PREGNANCY AND LACTATION :
Mucoprotec should be used by pregnant or possibly pregnant women only if the anticipated therapeutic benefit is thought to outweigh any potential risk. (The safety of rebamipide in pregnant women has not been established.)
Nursing should be interrupted when Mucoprotec is administered to a nursing woman. (Rat studies showed that rebamipide is distributed in the breast milk.)

CONTRAINDICATIONS :
Rebamipide is contraindicated in patients who have exhibited a history of hypersensitivity reaction to Rebamipide or to any of its components.

OVERDOSE AND TREATMENT :
Adult: Gastric Mucosal Lesions (Erosion, Bleeding, Redness and Edema) in Acute Gastritis and Acute Exacerbation of Chronic Gastritis: Usual Dose: 1 tab orally 3 times daily.
Gastric Ulcers: Usual Dose: 1 tab orally 3 times daily (in the morning, in the evening and before bedtime).

CAUTION :
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without a prescription.
Keep the medicine out of reach of children.

ADR Reporting Statement :
For suspected adverse drug reaction, report to the FDA : www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY :
Alu/clear PVC blister pack x 10's (Box of 100's)

STORAGE :
Store at temperatures not exceeding 30℃.

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Manufactured by :
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