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Raniplex™

H_2-RECEPTOR ANTAGONIST

Packs		Composition
Film-coated tablets 150mg	20	The active ingredient of Raniplex is Ranitidine (as Hydrochloride)
Film-coated tablets 300mg	10	

Properties

Raniplex inhibits basal and nocturnal gastric acid secretion by competitive inhibition of the action of histamine at the histamine H_2-receptors. It also inhibits gastric acid secretion stimulated by food and pentagastrin. A single oral dose of Raniplex 150mg significantly inhibits basal and pentagastrin-stimulated acid secretion for up to 12 hours.

Raniplex is readily absorbed from the gastro-intestinal tract with peak concentrations in plasma occurring 2 hours after oral administration. Food or antacids do not significantly affect the bioavailability of Raniplex after oral administration.

Raniplex is metabolised by the liver to desmethylranitidine, ranitidine-S-oxide and ranitidine-N-oxide. The drug and its metabolites are excreted principally in the urine.

Raniplex crosses the placental barrier. It is also excreted into breast milk.

Indications

Raniplex is indicated for the treatment of benign gastric ulcer, duodenal ulcer, post-operative ulcer, reflux oesophagitis, Zollinger-Ellison syndrome and conditions where reduction of gastric acidity is beneficial such as prophylaxis of gastro-intestinal haemorrhage as a consequence of stress ulceration and in patients at risk of acid aspiration (Mendelson's syndrome) during general anaesthesia.

Dosage

Adults: The usual oral dose of Raniplex is 150mg twice daily (in the morning and at bedtime). In the management of duodenal and gastric ulcers a single daily dose of 300mg by mouth at bedtime is suggested as an alternative to twice daily administration and treatment should be given initially for at least 4 weeks. In the majority of cases of duodenal ulcer, benign gastric ulcer and post-operative ulcer, healing occurs in four weeks. A further course of four weeks treatment may be required by some patients whose ulcers have not fully healed after the initial course of therapy. Where appropriate a maintenance dose of 150mg daily may be given at bedtime. In reflux oesophagitis the recommended dose is 150mg twice daily by mouth for up to 8 weeks. In patients with Zollinger-Ellison syndrome, the initial oral dose is usually 150mg two or three times daily and may be increased if necessary. Doses of up to 6g daily have been employed.

The recommended dose for the prophylaxis of gastro-intestinal haemorrhage as a consequence of stress ulceration is 150mg twice daily by mouth. In patients at risk for developing the acid aspiration syndrome during general anaesthesia, a dose of 150mg by mouth may be given 2 hours before the induction of anaesthesia or at the start of labour and may be repeated at intervals of 6 hours if required.

Side-effects

Minor side-effects occur infrequently and include headache and skin rashes that usually subside with continued therapy, malaise, nausea, constipation, dizziness and abdominal pain. Usual doses of Raniplex only rarely produce confusion, gynaecomastia, hyperprolactinemia, sexual dysfunction, bradycardia or hepatitis.

Precautions

It is vital to establish during treatment with Raniplex that gastric ulcer is not malignant as the drug may give symptomatic relief in gastric cancer and may temporarily heal the lesion. Since Raniplex is excreted primarily by the kidneys, dosage should be adjusted in patients with renal impairment. Caution should be observed in patients with liver dysfunction.

Pregnancy:

The safe use of Raniplex in pregnancy has not been established and therefore its use is not recommended.

Breast-feeding:

Raniplex is secreted in breast milk. Caution should be exercised when Raniplex is administered to a nursing mother.

Children:

Safety and effectiveness in children have not been established.

Drug Interactions:

Raniplex has been reported to decrease the absorption of Diazepam and Ketoconazole and to increase the absorption of Midazolam.

The concurrent administration of antacids with neutralising capacity above 40mEq may decrease the bioavailability of Raniplex. Lower doses of antacid may not affect bioavailability. Propantheline and other anticholinergics may delay the absorption and increase the serum concentration of Raniplex. It is recommended to allow at least one hour between administration of antacids or anticholinergics and Raniplex .

Laboratory Tests:

Serum transaminase and plasma creatinine levels increase but return to normal with continued treatment.

Raniplex may give false positive tests for urine protein with the Multistix method. Therefore testing with sulfosalicylic acid is recommended.

Contra-indications

Raniplex is contra-indicated in patients with known hypersensitivity to Ranitidine.

Overdosage

Since there is no specific antidote for overdose with histamine H_2-receptor antagonists, treatment is symptomatic and supportive with possible utilization of induction of emesis and/or use of gastric lavage, clinical monitoring, artificial respiration (in the event of respiratory failure) and administration of a beta-blocker, to control tachycardia.

Pharmaceutical Precautions

Storage Conditions:

Raniplex Tablets should be stored below 25°C, protected from light and moisture.

Incompatibilities:

None.

Do not use beyond the expiry date stated on container.

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