

RANITIN

(Ranitidine Tablets U.S.P., 150 mg & 300 mg)

Ranitine is a histamine H₂ receptor antagonist, which is indicated for the treatment of duodenal ulcer, gastric ulcer, maintenance therapy of duodenal and gastric ulcers, hypersecretory states such as Zollinger-Ellison syndrome and reflux disorders.

CLINICAL PHARMACOLOGY

Ranitine is a competitive inhibitor of histamine H₂ receptors. Both the acid secretion and volume of gastric secretion are suppressed by Ranitine, while changes in pepsin secretion are proportional to volume output. Ranitine inhibits both basal and nocturnal gastric secretion, as well as secretion stimulated by food and other stimuli. After oral administration the bioavailability of Ranitine averages about 50%. Absorption is not significantly affected by the administration of food and antacid. The half-life of Ranitine is 2-3 hours and is somewhat longer after oral than intravenous administration. The principle route of excretion is the urine. Approximately 30% of the orally administered dosage secreted as an unchanged drug.

INDICATIONS

1. Ranitine is indicated for treatment of acute duodenal ulcer and benign gastric ulcer.
2. Ranitine is used for maintenance therapy in duodenal ulcer and ulcer patients.
3. Ranitine is used for the treatment of pathological hypersecretory conditions like Zollinger-Ellison syndrome.
4. Ranitine is also indicated for various reflux diseases and drug induced ulceration.

CONTRAINDICATIONS

Ranitine is contraindicated in patients who are hypersensitive to it.

PRECAUTIONS

Treatment with histamine H₂ blockers may mask symptoms associated with carcinoma of the stomach, and may therefore delay diagnosis of the condition. Accordingly, where gastric ulcer has been diagnosed or in patients of middle age and above, with new or recently changed dyspeptic symptoms, the possibility of malignancy should be excluded. Ranitine should be administered with due precautions in patients with impaired renal functions.

USE IN PREGNANCY AND LACTATING MOTHER

Ranitine crosses the placenta but therapeutic doses to obstetric patients in labour, have been without any adverse effect on labour, delivery and subsequent neonatal progress.

Ranitine is also excreted from human breast milk. There are no adequate and well controlled studies of Ranitine during pregnancy. Therefore, Ranitine should only be used during pregnancy and in nursing mother if considered essential.

ADVERSE REACTIONS

The adverse reactions has been found similar to placebo and consist of headache, dizziness, constipation, diarrhoea, dry mouth, rashes, GI discomfort, nausea and fatigue. Transient and reversible changes in liver function tests can occur. Transient and reversible changes in liver function tests can occur. Hypersensitivity have been seen rarely. As with other H₂ blockers there have been reports of bradycardia and A-V block.

DOSAGE AND ADMINISTRATION

Usual dosage of Ranitine is 150 mg twice daily. Alternatively, it can be given as a single bedtime dose of 300 mg. Treatment should be continued for up to 4 to 8 weeks in most cases of duodenal ulcers, gastric ulcer and post operative ulcers and reflux oesophagitis. In case of NSAIDs induced ulceration, 150 mg at bedtime should be given.

In patients with Zollinger-Ellison syndrome, the starting dose is 150 mg thrice daily and this may be increased as necessary. Patients with this syndrome have been given increasing doses upto 6 gms/day and these doses have been well tolerated.

OVERDOSAGE

Ranitine is very specific in action and accordingly, no particular problems are expected following overdosage, and symptomatic and supportive therapy should be given as an appropriate therapy, if needed.

PRESENTATION

Ranitine is available as 150 mg and 300 mg film coated tablets in a strip of 10 tablets.



Manufactured by:
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