

Glotalc Tablets

Composition:

Glotalc Tablets 150 mg: Each tablet contains Ranitidine USP 150 mg (as Hydrochloride).

Glotalc Tablets 300 mg: Each tablet contains Ranitidine USP 300 mg (as Hydrochloride).

Properties:

Glotalc (Ranitidine) is a specific, rapidly acting histamine H₂-receptor antagonist. It inhibits both basal and stimulated gastric acid secretion, reducing the amount of gastric acid released, the total volume of gastric juice, and thereby indirectly decreasing pepsin secretion. Glotalc has a relatively long duration of action so a single 150 mg dose effectively suppresses gastric acid secretion for 12 hours.

Indications:

Glotalc is indicated for:

- Benign gastric ulcer and duodenal ulcer, including that induced by the use of non-steroidal anti-inflammatory agents.
- Duodenal ulcer associated with *Helicobacter pylori* infection.
- Prevention and prophylaxis of NSAIDs (including aspirin) induced duodenal ulcer, especially in patients with a history of peptic ulcer disease.
- Reflux oesophagitis.
- Zollinger-Ellison syndrome.
- Prophylaxis of stress ulceration in seriously ill patients.
- Prophylaxis of acid aspiration in obstetrics (Mendelson's syndrome).
- Prophylaxis of recurrent haemorrhage from peptic ulcer.
- Post operative ulcer.
- Chronic episodic dyspepsia.

Dosage and Administration:

Adults:

Benign gastric ulcer and duodenal ulcer.

Acute treatment: The standard dosage regimen is 150 mg twice daily, or 300 mg at night, for 4 to 8 weeks. In most cases healing occurs within 4 weeks. Healing usually occurs after a further 4 weeks in those patients not fully healed after the initial 4 weeks therapy. In duodenal ulcer Glotalc 300 mg tablet can be given twice daily for 4 weeks to achieve a higher healing rate.

Maintenance management: For long-term maintenance of benign gastric ulcer or duodenal ulcer, the recommended dosage regimen is Glotalc 150 mg tablet at night.

Duodenal ulceration associated with *Helicobacter pylori* infection:

Glotalc 300 mg tablet once at bedtime or Glotalc 150 mg tablet twice daily plus amoxicillin 750 mg 3 times daily and metronidazole 500 mg 3 times daily for two weeks. Therapy with Glotalc only should continue for a further two weeks. This dose regimen significantly reduces the frequency of recurrence of duodenal ulcer.

NSAIDs induced duodenal ulcer:

Acute treatment: In NSAIDs induced duodenal ulcer or associated with continued therapy, Glotalc 150 mg twice daily or Glotalc 300 mg at night for 8 weeks may be necessary.

Prophylaxis: For the prevention of NSAIDs associated duodenal ulcer, Glotalc 150 mg tablet twice daily may be given concomitantly with NSAIDs therapy.

Reflux oesophagitis:

Acute reflux oesophagitis: Glotalc 150 mg twice daily or Glotalc 300 mg tablet at bed time for up to 8 weeks, or if necessary for 12 weeks.

In patients with moderate to severe oesophagitis, the dosage may be increased to Glotalc 150 mg tablet four times daily for up to 12 weeks.

Long-term management of healed oesophagitis: The recommended adult dose is Glotalc 150 mg tablet twice daily.

Zollinger-Ellison syndrome:

The initial dosage regimen is Glotalc 150 mg tablet three times daily, but this may be increased as necessary. Doses up to 6 grams daily in divided doses have been used and well tolerated.

Prophylaxis of stress ulceration in seriously ill patients or prophylaxis of recurrent haemorrhage from peptic ulcer: Glotalc 150 mg tablet twice daily may be substituted for the injection when oral feeding commences.

Prophylaxis of acid aspiration in obstetrics patients at delivery (Mendelson's syndrome):

Glotalc 150 mg tablet at onset of labour, then every 6 hours.

Surgical prophylaxis:

For surgical prophylaxis, Glotalc 150 mg tablet 2 hours before induction of anaesthesia and also preferably Glotalc 150 mg tablet on the preceding evening.

Chronic episodic dyspepsia:

The standard regimen in younger patients is Glotalc 150 mg tablet twice daily for up to 6 weeks. Patients not responding or relapsing shortly afterwards should be investigated further. This regimen is undesirable in older patients as diagnosis of gastric cancer may be delayed.

Children:

The recommended oral dose for the treatment of peptic ulcer in children is 2-4 mg/kg twice daily to a maximum of 300 mg Ranitidine per day.

Contraindications:

Glotalc tablet is contraindicated in patients known to have hypersensitivity to Ranitidine. Glotalc tablets should be avoided in patients with a history of acute prophytia

Precautions:

When gastric ulcer is suspected, the possibility of malignancy should be excluded as treatment may mask symptoms of gastric carcinoma and delay diagnosis. In patients with severe renal impairment, it is recommended that Glotalc be administered in a dose of 150 mg at night for 4 to 8 weeks.

Use with caution in children less than 12 years of age. Long-term therapy may cause vitamin B12 deficiency.

Particular care is required in patients whose symptoms change during treatment and in those who are middle-aged or over.

Use in pregnancy and lactation:

Ranitidine crosses the placenta and is also excreted in breast milk. As with most drugs, Glotalc tablet should not be given during pregnancy and lactation unless the physician considers its use essential.

Side Effects:

Glotalc is generally well tolerated. The reported side effects include; transit and reversible altered liver function tests (rarely liver damage), headache, dizziness, rash, and tiredness. Rare side effects include acute pancreatitis, AV block, confusion, depression and hallucinations particularly in the elderly or the very ill, hypersensitivity reactions, and blood disorders. No clinically significant interference with endocrine or gonadal function has been reported. There have been rare reports of gynaecomastia and impotence in men taking ranitidine.

Rare cases of tachycardia, agitation, visual disturbances, erythema multiforme, and alopecia have been reported rarely.

Drug Interactions:

Glotalc reduces the absorption of the antifungal drugs ketoconazole and itraconazole.

Antacids may decrease the absorption of Ranitidine. Glotalc may produce altered serum levels of procainamide and ferrous sulfate. And may result in decreased absorption of cyanocobalamin. Increased toxicity of cyclosporin, gentamicin, gliptide, glyburide and quinidine has been reported rarely.

Presentation:

Glotalc 150 mg Tablets in packs of 20 tablets.

Glotalc 300 mg Tablets in packs of 10 tablets.

Store below 25°C in a dry place. Protect from light.

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not, by yourself, interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

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