Ranitidine 150mg

**Description:**
Norma-H is round film coated tablet containing ranitidine hydrochloride USP equivalent to 150mg ranitidine base.

**Indication:**
- Treatment of active duodenal ulcer
- Benign gastric ulcer
- Treatment and prevention of ulcer associated with nonsteroidal anti inflammatory agent.
- Post operative stress ulcer
- Zollinger-Ellison syndrome
- Gastro esophageal reflux disease (GERD)
- Gastro intestinal hemorrhage from stress ulcer in seriously ill patient.
- Recurrent hemorrhage in patients with bleeding peptic ulcer.
- Before general anesthesis in patient considered to be at risk of acid aspiration particularly obstetric patients

**Mode of Action:**
Ranitidine is a specific, rapidly acting histamine $H_2$-antagonist. It inhibits basal and stimulated secretion of gastric acid reduction both the volume and the acid and pepsin content of secretion. Ranitidine has a relatively long duration of action and so a single 150mg & 300mg dose effectively suppresses gastric acid secretion for twelve hours.

Absorption, Fate, and Excretion: As a group $H_2$ antagonists are rapidly well absorbed after oral administration; peak concentration in plasma are attained within 1 or 2 hours. The half-life for elimination of ranitidine, 2 to 3 hours. These drugs are in large part excreted in the urine without being metabolized. However, the half-life of ranitidine is significantly prolonged in patients with hepatic dysfunction.

**Dosage & Administration:**
Aduluts : The usual dosage is 150mg twice daily, taken in the morning and evening. Alternatively, patients with duodenal ulceration, gastric ulceration or esophageal reflux disease may be treated with a single bed time dose of 300mg. It is not necessary to time the dose in relation to meals. In most cases of duodenal ulcer, benign gastric ulcer and post-operative ulcer, healing occurs in four weeks. Healing usually occurs after a further four weeks of treatment in those patients whose ulcers have not fully healed after the initial course of therapy. For the prevention of non-steroidal anti-inflammatory drug associated duodenal ulcers, ranitidine 150mg twice daily may be given concomitantly with non-steroidal anti-inflammatory drug therapy.

In ulcers following non-steroidal anti-inflammatory drug therapy or associated with continued non-steroidal anti-inflammatory drugs, eight weeks treatment may be necessary. In duodenal ulcer 300mg twice daily for 4 weeks results in healing rates which are higher than those at 4 weeks with ranitidine 150mg twice daily or 300mg at night. The increased dose has not been associated with an increased incidence of unwanted effects.

Maintenance treatment at a reduced dosage of 150mg at bed time is recommended for patients who have responded to short-term therapy, particularly those with a history of recurrent ulcer. In the management of esophageal reflux disease, the recommended course of treatment is either 150mg twice daily or 300mg at bedtime for up to eight weeks or, if necessary, 12 weeks.

In patients with moderate to severe esophagitis, the dosage of ranitidine may be increased to 150 mg four times daily for up to twelve weeks. The increased dose has not been associated with an increased incidence of unwanted effects.

In patients with Zollinger-Ellison syndrome, the starting dose is 150mg three times daily and this may be increased as necessary. Patients with this syndrome have been given increasig doses up to 6 grams per day and these doses have been well tolerated. For Patients with chronic episodic dyspepsia the recommended course of treatment is 150mg twice daily for up to six weeks. Anyone not responding or relapsing shortly afterwards should be investigated.

In the prophylaxis of hemorrhage from stress ulceration in seriously ill patients or the prophylaxis of recurrent hemorrhage in patients bleading ulceration, treatment with Normal-H Tablets 150mg twice daily may be substituted for ranitidine injection once oral feeding commence in patients considered to be still at risk from these conditions.

In patients thought to be at risk of acid aspiration syndrome an oral dose of 150mg can be given 2 hours before induction of general anesthesis, and preferably also 150mg in the previous evening.

In obstetric patients at commencement of labor, an oral dose of 150mg may be given followed by 150 mg at six hourly intervals. It is recommended that since gastric emptying and drug absorption are delayed during labor, any patient requiring emergency general anesthesis should be given, in addition, a non-particulate antacid (e.g. sodium citrate) prior to induction of anesthesis. The usual precautions to avoid acid aspiration should also be taken.

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

**Contra-indication:**
Ranitidine is contra-indicated for patients known to have hypersensitivity to the drug.

**Precautions:**
Treatment with a histamine $H_2$-antagonist 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 over with new or recently changed dyspeptic symptoms the possibility of malignancy should be excluded before therapy with Norma-H tablets.

Ranitidine is excreted via the kidney and so plasma levels of the drug are increased in patients with severe renal impairment. Accordingly, it is recommended that the therapeutic regimen for Norma-H in such patients be 150mg at night for 4-8 weeks. The same dose should be used for maintaining treatment should this be deemed necessary. If an ulcer has not healed after treatment the standard dosage regimen of 150 mg twice daily should be instituted, followed, if need be, by maintenance treatment at 150mg at night.

Norma-H should be given in reduced dosage to patients with impaired renal function. It is removed by hemodialysis.

Regular supervision of patients who are taking non-steroidal anti-inflammatory drugs concomitantly with ranitidine is recommended, specially in the elderly. Current evidence shows that ranitidine protects against NSAID associated ulceration in the duodenum but not in the stomach.

Caution should be observed in patient with hepatic dysfunctions, since Norma-H is metabolized in liver. There is prolongation of half life in hepatic dysfunctions.

Norma-H crosses the placenta but therapeutic doses administered to obstetric patients in labor or undergoing caesarean section have been without any adverse effect on labor, delivery or subsequent neonatal progress. Norma-H is also excreted in human breast milk. Like other drugs, Norma-H should only be used during pregnancy, if considered essential. Ranitidine is excreted in the milk, hence precaution should be taken when given to a nursing mother.

**Side-effects:**
Transient and reversible changes in liver function tests can occur. There have been occasional reports or hepatitis (hepatocellular, hepatocapuliccular or mixed) with or without jaundice. These were usually reversible. Acute pancreatitis has been reported rarely.

Leucopenia and thrombocytopenia have rarely been in patients. These are usually reversible. Rare case or agranulocytosis or of pancytopenia, sometimes with marrow hypoplasia, or alpasia have been reported.

Hypersensitivity reactions (urticaria angioneurotic oedema, fever, bronchospasms hypotension anaphylactic shock) have been seen rarely following the parenteral and oral administration of ranitidine. These reaction have occasionally occurred after a single dose. As with other $H_2$-receptor antagonist, there have been rare reports of bradycardia and A-V block.

Headache, sometimes severe, and dizziness have been reported in a very small proportion of patients. Late cases of reversible mental confusion and hallucinations have been reported, predominantly in severely ill and elderly patients.

Skin rash and arthralgia have been rarely reported.

No clinically significant interference with endocrine or gonadal function have been reported. There have been few reports of breast symptoms (swelling and / or discomfort) in men taking ranitidine, some cases have resolved on continued ranitidine treatment. Discontinuation of therapy may be necessary in order to establish the underlying cause.

**Use in elderly patients:** Rates of healing of ulcers in clinical trial patients aged 65 and over have not been found to differ from those in younger patients. Additionally, there was no difference in the incidence of adverse effects.

**Overdosage:** Norma-H is very specific in action and accordingly no particular problems are expected following overdosage with the drug. Symptomatic and supportive therapy should be given as appropriate. If need be, the drug may be removed from the plasma by haemodialysis.

Ranitidine decreases the actions of lignocaine, phenytoin, propranolol, theophylline warfarine.

**Supply:** Box Containing 10x10 tablets in Alu Alu Blister pack.