Normacid

Ranitidine Hydrochloride USP

Composition:
Normacid Tablet: Each film-coated tablet contains Ranitidine HCl USP equivalent to Ranitidine 150 mg.
Normacid Syrup: Each 5 ml sugar free syrup contains Ranitidine HCl USP equivalent to Ranitidine 75 mg.
Normacid Injection: Each 2 ml ampoule contains Ranitidine HCl USP equivalent to Ranitidine 50 mg.

Description:
Normacid is histamine (H_2) receptor antagonist. It is indicated for the short-term treatment of duodenal ulcer and the management of hypersecretory conditions such as Zollinger-Ellison Syndrome and systemic astocytosis. Normacid is readily absorbed from the GIT with peak concentration in plasma occurring about 2 hours after administration by mouth. The bioavailability of Normacid following oral administration is about 50%. The half-life of Normacid is about 2 hours and is weakly bound to plasma proteins. A small proportion of Normacid is metabolized in the liver and most of the dose is excreted unchanged in the urine.

Indications:
- Benign gastric and duodenal ulcer
- Gastro-Esophageal Reflux Disease (GERD)
- Zollinger-Ellison Syndrome (ZES)
- Erosive esophagitis
- Pathological hypersecretory conditions
- Chronic episodic dyspepsia
- NSAIDs-induced ulcer
- Prophylaxis of Mendelson's Syndrome
- Prophylaxis of Haemorrhage from stress ulceration in seriously ill patients

Dosage and Administration:
Oral (Tablet/Syrup):
Duodenal Ulcer: 1 tablet (150 mg)/2 tea-spoonful twice daily or 2 tablets/4 tea-spoonful at night for 4 to 8 weeks.
Maintenance dose: 1 tablet (150 mg)/2 tea-spoonful at night.
Child (peptic ulcer): 2-4 mg/kg body weight twice daily. Maximum 2 tablet/4 tea-spoonful daily.
Reflux esophagitis: 1 tablet (150 mg)/2 tea-spoonful twice daily or 2 tablets (300 mg) / 4 tea-spoonful at night for up to 8 weeks.
Zollinger-Ellison Syndrome: 1 tablet (150 mg) or 2 tea-spoonful three times daily up to 6 gm daily in three divided doses.
Gastric acid reduction in labour: 1 tablet (150 mg) or 2 tea-spoonful at onset of labour.
Injection:
Adults
- a slow (over a period of at least two minutes) intravenous injection of 50 mg (2 ml), after dilution to a volume of 20 ml per 50 mg dose, which may be repeated every six to eight hours;
- an intermittent intravenous infusion at a rate of 25 mg (1 ml) per hour for two hours; the infusion may be repeated at six to eight hour intervals
- an IM injection of 50 mg (2 ml) every six to eight hours.

Prophylaxis of Mendelson's Syndrome:
50 mg (2 ml) may be given intramuscularly or by slow intravenous injection 45 to 60 minutes before induction of general anaesthesia.
Prophylaxis of Haemorrhage from stress ulceration in seriously ill patients:
In the prophylaxis of haemorrhage from stress ulceration in seriously ill patients, parenteral administration at mentioned dose may be continued until oral feeding commences. Patients considered to be still at risk may then be treated with 1 tablet (150 mg) twice daily.
In the prophylaxis of upper gastrointestinal haemorrhage from stress ulceration in seriously ill patients, a priming dose of 50 mg (2 ml) as a slow intravenous injection followed by continuous intravenous infusion of 0.125-0.250 mg/kg/hour is preferred.
Children
The use of Ranitidine Injection in children less than 6 months has not been evaluated. Safety and efficacy in neonates has yet not been established.

Precaution and Warning:
The doses should be reduced in patients with impaired renal function. Caution should be taken in patients with hepatic dysfunction. It should be avoided in patients with a history of acute porphyria.

Side-effects:
Reversible confusion, headache, malaise, constipation, diarrhoea, hepatitis, thrombocytopenia, and leucopenia. It may also rarely causes tachycardia, bradycardia and premature ventricular beats.

Contraindication:
Normacid is contraindicated in patients with known history of hypersensitivity to Ranitidine.

Use in Pregnancy and Lactating mother:
It should be used during pregnancy only if clearly indicated. As ranitidine is secreted in human milk, caution should be exercised when it is administered to a nursing mother.

Pharmaceutical Precaution:
Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Supply:
Normacid Tablet : Each box contains 10 x 10 tablets in Alu-Alu blister packs.
Normacid Syrup : Each bottle contains 100 ml of syrup.
Normacid Injection : Each box contains 2 x 5 ampoules in Alu-Alu blister packs.

Manufactured by :
KEMIKO
KEMIKO PHARMACEUTICALS LTD.
Bangladesh