Peptil H®

Ranitidine Hydrochloride USP
Film Coated Tablet, Syrup and Injection

DESCRIPTION

Peptil H® is a preparation of Ranitidine. It is a specific, rapidly acting H_2 receptor antagonist. It inhibits basal and stimulated secretion of gastric acid, reducing both the volume and the acid and pepsin content of the secretion. Peptil H® has a relatively long duration of action and so a single 150 mg dose effectively suppresses gastric acid secretion for twelve hours.

INDICATIONS

PeptilH® is indicated in the following conditions:

- Duodenal ulcer and benign gastric ulcer, Including that associated with non-steroidal anti-inflammatory agents.
- Prevention of non-steroidal anti-inflammatory drug associated duodenal ulcers.
- Treatment of duodenal ulcers associated with *Helicobacter pylori* infectlon.
- Post-operative ulcer.
- Oesophageal reflux disease including long term management of healed oesophagitis.
- Symptomatic relief in gastro-oesophageal reflux disease.
- Zollinger-Ellison Syndrome.
- Chronic episodic dyspepsia, characterised by pain (epigastric or retrosternal) which is related to meals or disturbs sleep but not associated with the above conditions.
- Prophylaxis of gastrointestinal haemorrhage from stress ulceration.
- Prophylaxis of recurrent haemorrhage with bleeding peptic ulcers.
- Before general anaesthesia in patients at risk of acid aspiration (Mendelson's syndrome), particularly obstetric patients during labour.

DOSAGE AND ADMINISTRATION

Oral: ***Adults (Including the elderly):***

- Usual dosage: 150 mg twice daily taken in the morning and at bed time or 300 mg at bed time for 4 weaks; maintenance dose of 150 mg at night may be given.
- In duodenal ulcer or benign gastric ulcer: 300 mg once daily at bed time or 150 mg twice daily taken in the morning and before retiring for 4 weeks.
- In patients with moderate to severe oesophagitis: The dosage of Ranitidine may be increased to 150 mg 4 times daily for up to 12 weeks.
- The starting dose for Zollinger-Ellison syndrome: 150 mg three times daily and this may be increased as necessary.
- In patients thought to be at risk of acid aspiration syndrome: an oral dose of 150 mg can be given 2 hours before induction of general anaesthesia and preferably also 150 mg the previous evening.
- In obstetric patients at commencement of labour: an oral dose of 150 mg may be given followed by 150 mg at six hourly intervals.

Children:

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

Injection:

Adult:

- I.M. Injection: 50 mg (2 ml) every 6 to 8 hours (no dilution is required).
- Intermittent I.V. Bolus: 50 mg (2 ml) every 6 to 8 hours. Dilute the Injection, 50 mg in 0.9% sodium chloride or other compatible I.V. solution to a total volume of 20 ml and at a concentration not greater than 2.5 mg/ml. Inject over a period not less than 5 minutes (4 ml/min).
- Intermittent I.V. Infusion: 50 mg (2 ml) every 6 to 8 hours. Dilute the injection, 50 mg, in 5% dextrose injection or other compatible I.V. solution to a total volume of 100 ml and at a concentration not greater than 0.5 mg/ml. Infuse over 15-20 minutes.
- Continuous Intravenous Infusion: Add the injection to 5% dextrose or other compatible I.V. solution to a concentration 0.125 to 0.250 mg/kg/hr.

Children:

While limited data exist on the administration of I.V. Ranitidine to children, the recommended dose in paediatric patients is for a total daily dose of 2 to 4 mg/kg, to be divided and administered every 6 to 8 hours, up to a maximum of 50 mg given every 6 to 8 hours. Limited data in neonatal patients (less than 1 month of age) receiving ECMO have shown that a dose of 2 mg/kg is usually sufficient to increase gastric pH to> 4 for at least 15 hours. Therefore, doses of 2 mg/kg given every 12 to 24 hours or as a continuous infusion should be considered.

CONTRAINDICATIONS

Ranitidine Hydrochloride is contraindicated for patients known to have hypersensitivity to the active ingredient.

SIDE EFFECTS

Headache, skin rashes, dizziness, hypersensitivity reactions, reversible mental confusion, leukopaenia and thrombocytopenia have occurred rarely in patients and have reversed on drug withdrawal.

PRECAUTIONS

Should be given in reduced dosage in patients with impaired renal function. Ranitidine crosses the placenta and is excreted in breast milk. Like other drugs, Ranitidine should be used during pregnancy and lactation if considered essential.

PHARMACEUTICAL PRECAUTION

Tablet : Store in a dry place and away from light.
Syrup : Store below 25°C, away from light. Do not freeze.
Injection : Store below 25°C, dry place and protect from light. Do not freeze. Keep out of reach of children.

PACKAGING

Peptil H® 150 Tablet : Box containing 10/15 strips of 10 tablets each. Each film coated tablet contains Ranitidine Hydrochloride USP equivalent to 150 mg Ranitidine.

Peptil H® Syrup : Bottle containing 100 ml syrup. Each 5 ml syrup contains Ranitidine Hydrochloride USP equivalent to 75 mg Ranitidine.

Peptil H® Injection : Box containing 2 strips of 5 ampoules each. Each 2 ml ampoule contains Ranitidine Hydrochloride USP equivalent to Ranitidine 50 mg.

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