ROLAN®

(Ranitidine HCl)

ACTION

Rolan is a specific reversible competitive blocker of histamine H2 receptors. Rolan is a rapidly acting histamine H2 antagonist that reduces gastric acid secretion under daytime and nocturnal basal conditions and also when stimulated by food. Rolan has a relatively long duration of action and a single Rolan 150 mg tablet effectively suppresses gastric acid secretion for twelve hours.

INDICATIONS

- *Duodenal ulcer*: short term treatment and maintenance therapy.
- *Gastric ulcer*: short term treatment and maintenance therapy.
- *Gastroesophageal reflux disease*.
- *Erosive esophagitis*: Treatment and maintenance of healing.
- *The treatment of pathological hypersecretory conditions* (e.g Zollinger-Ellison syndrome).
- *Before general anaesthesia in patients considered to be at risk for acid aspiration (Mendelson's syndrome), especially obstetric patients during labour.*

DOSAGE AND ADMINISTRATION

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 4 weeks of treatment in those patients whose ulcers have not fully healed after the initial course of therapy.

Injection

- Rolan injection is given either as a slow (over a period not less than 2 minutes) IV injection of 50 mg, after dilution to a volume of 20 ml, which may be repeated every 6-8 hours; or as an intermittent IV infusion at a rate of 25 mg/hour for 2 hours, which may be repeated every 6-8 hours; or as an intramuscular injection at a rate of 50 mg (2ml) which may be repeated every 6-8 hours.
- In the prophylaxis for upper gastro-intestinal haemorrhage from stress ulceration, a primary dose of 50 mg as a slow IV injection followed by continuous IV infusion of 0.125-0.250 mg/kg/hr may be preferred.
- In patients considered for risk for developing acid aspiration, 50 mg injection may be given IM or as slow IV injection at a period 45-60 minutes before anaesthesia induction.

Tablets

Duodenal ulcer:

Short- term treatment of active duodenal ulcer: one tablet of Rolan 150 orally twice daily. An alternate dosage of Rolan 300 once daily at bedtime can be used for patients in whom dosing convenience is important.

Maintenance: one tablet of Rolan 150 at bedtime.

Gastric Ulcer:

Benign, active: either one tablet of Rolan 150 twice a day or one tablet Rolan 300 mg at bedtime.

Maintenance: one tablet of Rolan150 at bedtime.

Gastroesophageal Reflux Disease:

The current recommended adult oral dosage is one tablet of Rolan 150 mg twice daily.

Erosive Esophagitis:

Treatment: one tablet of Rolan 150 mg four times a day.

Maintenance: one tablet of Rolan 150 mg twice daily.

Pathological Hypersecretory Conditions (such as Zollinger-Ellison syndrome):

The current recommended adult oral dosage is one tablet of Rolan 150 mg twice a day. In some patients it may be necessary to administer Rolan more frequently. Dosages should be adjusted to individual patients needs, and should continue as long as clinically indicated. Dosage up to 6 g Ranitidine (40 tablets of Rolan 150) per day have been employed in patients with severe disease.

CONTRAINDICATIONS

Ranitidine is contraindicated in patients known to have hypersensitivity to the drug.

WARNINGS

Treatment with a histamine H2-antagonist may mask symptoms associated with carcinoma of the stomach and may therefore delay diagnosis of the condition. Accordingly, where gastric ulcer is suspected the possibility of malignancy should be excluded before therapy with H2 antagonist is instituted. The recommended therapeutic regimen for Rolan in patients with severe renal failure is as follows:

Tablets: 150 mg bedtime. The same dose should be used for maintenance treatment should this be deemed necessary.

Injection: doses of 25 mg are recommended.

PRECAUTIONS

Ranitidine injection is compatible with the following intravenous infusion fluids.

0.9% Sodium Chloride BP, 5% Dextrose BP, 0.18% Sodium Chloride and 4% Dextrose BP, 4.2% Sodium Bicarbonate BP and Hartmann's solution. All unused mixtures of Rolan injection with infusion fluids should not be used 24 hours after preparation.

Pregnancy (FDA Category B): Reproduction studies in rats and rabbits using Ranitidine up to 160 times the usual human dosage have not revealed evidence of impaired fertility or harm to the foetus There are no adequate and controlled studies to date using Ranitidine in pregnant women. Ranitidine crosses the placenta but therapeutic doses administered to obstetric patients in labour or undergoing caesarean section have been without any adverse effect on labour, delivery or subsequent neonatal progress.

Lactation: Ranitidine is excreted in breast milk so caution should be exercised when administering to nursing mother.

Children: Safety and efficacy of Ranitidine in children younger than 6 years of age have not been fully evaluated in clinical studies.

- *Renal impairment* : the recommended dosage in patients with creatinine clearance <50 ml/min is 50 mg every 18 to 24 hours. Should the patient's condition require the frequency of dosing may be increased to every 12 hours or further with caution.
- Caution should be observed in patients with hepatic dysfunction since Ranitidine is metabolized in the liver.

Drug Interactions:

Ranitidine does not inhibit the action of the cytochrome P-450- linked oxygenase enzyme in the liver when it's taken within the recommended doses of the drug.

Accordingly, Ranitidine does not potentiate the actions of drugs, which are inactivated by this enzyme; this include warfarin, theophylline, diazepam, propranolol, phenytoin, and lignocaine.

SIDE EFFECTS

Adverse effects of Ranitidine are generally infrequent and minor. They include rare cases of headache (sometimes severe), dizziness, gastro-intestinal disturbances. Transient and reversible changes in liver function tests can occur. Reversible leukopaenia and thrombocytopaenia have occurred rarely in patients on Ranitidine.

Hypersensitivity reactions and tachycardia have been rarely reported. Reversible mental confusion have rarely been reported with elderly patients.

OVERDOSAGE

There is no experience with deliberate overdosage to date with Ranitidine. Reported ingestions of up to 18 g Ranitidine (120 tablets of Rolan 150) HCl have been associated with transient adverse effects. In case of overdosage, symptomatic and supportive therapy should be given as appropriate. If need be, the drug may be removed from the plasma by haemodialysis.

PRESENTATION

Tablets

ROLAN 150:	Ranitidine (as HCl) USP 150 mg/tablet
ROLAN 300:	Ranitidine (as HCl) USP 300 mg/tablet

Ampoules

ROLAN 50:	Ranitidine (as HCl) USP 50 mg/2 ml

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, 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 medicament out of the reach of children

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