

RANIMED® Syrup

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about RANIMED

RANIMED is available in 2 dosages; 5 mg/mL and 10 mg/mL.

Each 5 mL of RANIMED 5 mg/mL syrup contain 25 mg ranitidine (as ranitidine HCl).

Each 5 mL of RANIMED 10 mg/mL syrup contain 50 mg ranitidine (as ranitidine HCl).

RANIMED syrup is for oral use.

Ranitidine is a competitive, reversible inhibitor of the action of histamine at the histamine H₂-receptors, including receptors on the gastric cells. It inhibits basal and stimulated secretion of gastric acid.

RANIMED is indicated in the following conditions:

- Treatment of gastroesophageal reflux disease and erosive esophagitis
- Treatment of duodenal and gastric ulcers
- Maintenance of healing of duodenal and gastric ulcers

RANIMED can also be used for other conditions where gastric acid reduction is beneficial such as protection from drug-induced gastroduodenal injury in children.

The way to take RANIMED

RANIMED must be administered as directed by your doctor. Dosage is generally individualized according to the child's weight. Do not exceed the maximum recommended dosage. RANIMED is administered without regard to meals or feeding schedule.

The safety and effectiveness of this drug have been established in the age group of 1 month to 16 years. The usual recommended daily dosage is:

- *Treatment of gastroesophageal reflux disease and erosive esophagitis:* 5 to 10 mg/kg/day, usually given as two divided doses (2.5 to 5 mg/kg twice daily)
- *Treatment of duodenal and gastric ulcers:* the recommended oral dose for the treatment of active duodenal and gastric ulcers is 4 to 8 mg/kg/day (2 to 4 mg/kg twice daily) to a maximum of 300 mg/day
- *Maintenance of healing of duodenal and gastric ulcers:* 2 to 4 mg/kg/day once daily to a maximum of 150 mg/day

The following chart suggests the average recommended dosage according to the child's weight:

Child's weight	Treatment of gastroesophageal reflux disease 5 to 10 mg/kg/day		Treatment of active duodenal and gastric ulcers 4 to 8 mg/kg/day		Maintenance of healing of duodenal and gastric ulcers 2 to 4 mg/kg/day	
	5 mg / mL	10 mg / mL	5 mg / mL	10 mg / mL	5 mg / mL	10 mg / mL
2.5 kg to less than 5 kg	12.5 mg (2.5 mL) twice daily	12.5 mg (1.25 mL) twice daily	10 mg (2 mL) twice daily	10 mg (1 mL) twice daily	10 mg (2 mL) once daily	10 mg (1 mL) once daily
5 kg to less than 10 kg	25 mg (5 mL) twice daily	25 mg (2.5 mL) twice daily	20 mg (4 mL) twice daily	20 mg (2 mL) twice daily	20 mg (4 mL) once daily	20 mg (2 mL) once daily
10 to 20 kg	50 mg (10 mL) twice daily	50 mg (5 mL) twice daily	40 mg (8 mL) twice daily	40 mg (4 mL) twice daily	40 mg (8 mL) once daily	40 mg (4 mL) once daily

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Administer the missed dose to your child as soon as you remember unless the next intake is near. Go on giving the next scheduled dose as directed. Do not administer a double dose at once.

Contraindications

This drug is contraindicated in case of known hypersensitivity to any of the components.

Precautions

- Dosage should be adjusted in patients with impaired renal function. Caution should be observed in patients with hepatic dysfunction.
- This drug should be avoided in patients with a history of acute porphyria.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently. Antacids and sucralfate should not be taken within the two-hour period before or after taking this drug.

Adverse reactions

This drug is generally well tolerated when used as directed. In rare cases it may cause headache, abdominal discomfort or pain, nausea, vomiting, constipation, diarrhea or rash. Inform your doctor if any of these effects appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

RANIMED, ranitidine 5 mg / mL, bottle of 100 mL with a dosing cup

RANIMED, ranitidine 10 mg / mL, bottle of 100 mL with a dosing cup

Revision date: 12/2009

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