RANIDINE CHAPHA®

COMPOSITION
Active ingredient:
Ranitidine HCl ……..equivalent to 25mg/5mL Ranitidine.
Excipients:
monobasic potassium phosphate, dibasic sodium phosphate, sorbitol (non crystallizing), glycerol, sucralose, propyl & butyl parabens, sodium chloride, ethanol, banana flavor, & purified water.

PHARMACEUTICAL FORM
Oral solution, 100mL bottle.

PHARMACOTHERAPEUTIC CLASS
Histamine H2-receptor antagonist.

PHARMACOLOGICAL ACTION
Ranitidine acts as a competitive inhibitor of histamine at H2-receptors of the gastric parietal cells, thus it inhibits gastric acid secretion, and it reduces hydrogen ion concentration.
Ranitidine inhibits both basal and stimulated gastric acid secretion. It does not affect pepsin secretion. Total pepsin output is reduced in proportion to the decrease in volume of gastric juice. Ranitidine has little or no effect on fasting or postprandial serum gastrin.

PHARMACOKINETICS
Ranitidine is 50% absorbed after oral administration with maximum concentration achieved after approximately 2 to 3 hours. It undergoes an enterohepatic recirculation process.
Ranitidine is weakly bound (15%) to plasma proteins. It minimally penetrates the blood-brain barrier and it enters breast milk.
Ranitidine is a minor substrate of CYP2C19, 2D6 and 1A2. It is essentially eliminated by renal excretion, with approximately 30% of the administered dose excreted as unchanged drug. The metabolites are mainly excreted in the feces.
The approximate half-life is 2.5 to 3 hours and up to 4.8 hours in patients with renal impairment.

INDICATIONS
Ranidine Chapha® is indicated in:
• Treatment of gastroesophageal reflux disease and erosive esophagitis;
• Short-term treatment of active duodenal and gastric ulcers;
• Maintenance of healing of duodenal and gastric ulcer.

ADVERSE REACTIONS
Ranidine Chapha® is generally well tolerated.
In rare cases, it may cause headache, abdominal discomfort or pain, nausea, vomiting, constipation, diarrhea or rash.

OVERDOSAGE
In case of overdosage, the usual measures to remove unabsorbed material from the gastrointestinal tract, clinical monitoring, and supportive therapy should be employed.

DRUG INTERACTIONS
Please inform your doctor if other medicines are being taken concommitantly with Ranidine Chapha®.

PRECAUTIONS
Efficacy and safety of Ranitidine in children under 1 month of age have not been established.
Dosage should be adjusted in patients with impaired renal function; and caution should be observed in patients with hepatic dysfunction.
Avoid in patients with acute porphyria.

CONTRA - INDICATIONS
Hypersensitivity to Ranitidine or to any of the excipients.

DOSAGE AND ADMINISTRATION
Ranidine Chapha® can be taken regardless of mealtime.
The following suggested dosage is safe and effective in the age group of 1 month to 16 years:
• Treatment of gastroesophageal reflux disease and erosive esophagitis: 2.5-5mg/Kg twice daily;
• Treatment of active duodenal and gastric ulcers: 2-4mg/Kg twice daily up to a maximum of 300mg/day;
• Maintenance of healing of duodenal and gastric ulcers: 2-4mg/Kg once daily up to a maximum of 150mg/day.

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

Child's Weight	Treatment of gastroesophgeal reflux disease	Treatment of active duodenal and gastric ulcers	Maintenance of healing of duodenal and gastric ulcers
2.5Kg to less than 5Kg	2.5mL (12.5mg) twice daily	2mL (10mg) twice daily	2mL (10mg) once daily
5Kg to less than 10Kg	5mL (25mg) twice daily	4mL (20mg) twice daily	4mL (20mg) once daily
10Kg to less than 20Kg	10mL (50mg) twice daily	8mL (40mg) twice daily	8mL (40mg) once daily

Ranidine Chapha® may also be used by adults as recommended by physicians.

CONSERVATION
All medicines should be kept out of children's reach.
Do not use when expired (expiry date on the box).
Keep in a dry cool place at room temperature under 25°C, and protect from light.

CHAPHA
(Chalhoub Pharmaceuticals) S.A.L.
Made in Lebanon