



ZIDAN®

Ranitidine Hydrochloride Injectable solution, Ampoules

Composition

Each ampoule of 2 ml contains:

Active ingredient: Ranitidine Hydrochloride equivalent to Ranitidine 50 mg.

Excipients: Dibasic sodium phosphate, monobasic potassium phosphate, phenol and water for injection.

Properties

The active component of **Zidan**, ranitidine, is a histamine H₂-receptor antagonist that inhibits histamine-induced gastric acid secretion. **Zidan** reduces both the volume and concentration of gastric acid secretion induced nocturnally and by food, and reduces pepsin output.

Zidan is a rapidly acting H₂ antagonist with a relatively long duration of action.

Indications

Zidan is indicated in:

- The treatment of duodenal ulcer.
- The treatment of benign gastric ulcer.
- The treatment of gastro-esophageal reflux disease.
- The relief of persistent dyspepsia with or without peptic ulceration.
- The treatment of pathological hypersecretory conditions such as Zollinger-Ellison syndrome.

Zidan ampoules are especially indicated when a quick response is required and/or oral feeding is not possible such as:

- Prophylaxis of gastro-intestinal hemorrhage from stress ulceration in seriously ill patients.
- Prophylaxis of recurrent hemorrhage in patients with bleeding peptic ulcers.
- Before general anesthesia in patients considered to be at risk of acid aspiration, particularly obstetric patients during labour.

Children (6 months to 18 years):

Zidan is indicated for the short term treatment of peptic ulcer and the treatment of gastro-oesophageal reflux, including reflux oesophagitis and symptomatic relief of gastro-oesophageal reflux disease.

Dosage and administration

Adults and adolescents (12 years and over):

Zidan may be given as:

- A slow intravenous injection: 50 mg (for at least two minutes), after dilution to a volume of 20 ml per 50 mg dose, which may be repeated every 6-8 hours.
- An intermittent intravenous infusion: 25 mg per hour for 2 hours; the infusion may be repeated at 6-8 hour intervals.
- An intramuscular injection: 50 mg (2 ml) every 6-8 hours.

In the prophylaxis of hemorrhage from stress ulceration in seriously ill patients or the prophylaxis of recurrent hemorrhage in patients bleeding from peptic ulceration, parenteral administration may be continued until oral feeding commences.

In the prophylaxis of upper gastro-intestinal hemorrhage from stress ulceration in seriously ill patients, a priming dose of 50 mg, as a slow intravenous injection, followed by a continuous intravenous infusion of 0.125-0.250 mg/kg/hr may be preferred.

In patients considered to be at risk of developing acid aspiration syndrome, **Zidan** injection 50 mg may be given intramuscularly or by slow intravenous injection, 45 to 60 minutes before induction of general anesthesia.

Children / Infants (6 months to 11 years):

Zidan may be given as a slow (over 2 minutes) I.V. injection up to a maximum of 50 mg every 6 to 8 hours.

Intravenous therapy in children with peptic ulcer disease is indicated only when oral therapy is not possible.

For acute treatment of peptic ulcer disease and gastro-oesophageal reflux in paediatric patients, the initial dose of **Zidan** (2.0 mg/kg or 2.5 mg/kg, maximum 50 mg) may be administered as a slow intravenous infusion over 10 minutes, either followed by a 3 mL flush with normal saline over 5 min, or following dilution with normal saline to 20 mL. Maintenance of pH > 4.0 can be achieved by intermittent infusion of 1.5 mg/kg every 6 h to 8 h. Alternatively treatment can be continuous, administering a loading dose of 0.45 mg/kg followed by a continuous infusion of 0.15 mg/kg/hr.

Contra-indications

Zidan is contra-indicated in patients known to be hypersensitive to ranitidine.

Precautions

Symptomatic response to ranitidine therapy should not preclude the presence of gastric malignancy. Since ranitidine is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function. A regimen of 150 mg at night for 4-8 weeks is recommended.

Caution should be observed in patients with hepatic dysfunction since ranitidine is metabolized in the liver.

Like other drugs, ranitidine should only be used during pregnancy and nursing if considered essential.

Bradycardia in association with rapid administration of ranitidine injection has been reported rarely and only in predisposed patients.

Higher than recommended intravenous doses of H₂ antagonists have been associated with rises in liver enzymes when treatment has been extended beyond 5 days.

Side effects

Ranitidine is usually well tolerated. Minor adverse effects occur infrequently and include headache, malaise, nausea, constipation, dizziness and skin rashes that usually subside with continued therapy. Transient increases in serum transaminase and plasma creatinine levels have been reported.

Hypersensitivity reactions have been seen rarely following the parenteral and oral administration of ranitidine.

Drug interactions

Ranitidine may decrease the absorption of diazepam and reduce its plasma concentration.

The concurrent administration of antacids with high neutralizing capacity may decrease the bioavailability of ranitidine.

Anticholinergic drugs may delay the absorption of ranitidine and increase its bioavailability.

Presentation

Zidan injectable solution is available in packs of 5 or 50 ampoules of 2 ml.

Storage conditions

Store below 25°C. Protect from light.

**ARWAN Pharmaceutical Industries Lebanon s.a.l.,
Jadra, Lebanon**

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their 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 all medicaments out of the reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**