VCI
Draft - 13 Jun 19

Peptic Ulcer Preparation

VCI MYS-003
R.O.C. Reg. No.:031327

VESYCA INJECTION 25MG/ML

Ingredient(s):
Each mL contains:
Ranitidine (as Hydrochloride) ..... 25 mg
Methyl Paraben (as preservative) ..... 1.8 mg
Propyl Paraben (as preservative) ..... 0.2 mg
Benzyl Alcohol (as preservative) ..... 0.01 mL

Pharmacodynamics:
Ranitidine is a specific, rapidly acting histamine H_2-antagonist. It inhibits basal and nocturnal gastric acid secretion by competitive inhibition of the action of histamine at the histamine H_2-receptors of the parietal cells. It reduces both the volume and the acid and pepsin content of the secretion. It also inhibits gastric acid secretion stimulated by food, betazole, pentagastrin, caffeine, insulin and physiological vagal reflex. Ranitidine has a relatively long duration of action and so a single 150 mg dose effectively suppresses gastric acid secretion for 12 hours.

Pharmacokinetics:
Absorption of ranitidine after intramuscular injection is rapid and peak plasma concentrations are usually achieved within 15 min of administration.
Ranitidine is not extensively metabolized. Elimination of ranitidine is primarily by tubular secretion. The elimination half-life is 2-3 hours.
A small proportion of ranitidine is metabolized in the liver to the N-oxide, the S-oxide, and desmethylranitidine; the N-oxide is the major metabolite but accounts for only about 4% of a dose.
Approximately 70% of an intravenous dose is excreted unchanged in the urine by active transport in 24 hours; there are some excretions in the faeces. Clearance is markedly reduced in severe renal impairment.

Indication(s):
Treatment of duodenal ulcer, benign gastric ulcer, postoperative ulcer, reflux oesophagitis and Zollinger-Ellison syndrome. Prophylaxis of gastrointestinal haemorrhage from stress ulceration in seriously ill patients, prophylaxis of recurrent haemorrhage in patients with bleeding peptic ulcers and before general anaesthesia in patients considered to be at risk of acid aspiration, particularly obstetric patients during labour.

Dosage and Administration:
Intramuscular injection:
50 mg (2mL) every 6 to 8 hours (dilution is not necessary).
Slow intravenous injection:
50 mg (2 mL), every 6 to 8 hours. Dilute Vesyca Injection 50 mg in 0.9% Sodium Chloride injection or other compatible I.V. solution to a total volume of 20 mL and inject over a period of not less than 2 minutes.
Intermittent intravenous infusion:
25 mg (1 mL) per hour for 2 hours. The infusion may be repeated at 6- to 8-hours intervals.
For patients with impaired renal function (creatinine clearance < 50 mL/min):
Intravenous, 50 mg (2 mL) every 18 to 24 hours, the frequency of the dosage being increased to every 12 hours or more frequently, if necessary. Further reduction in dosage may be required if hepatic function impairment is also present.
For prophylaxis of haemorrhage from stress ulceration in seriously ill patients:
Initially, 50 mg as slow I.V. injection followed by a continuous I.V. infusion of 0.125-0.25 mg/kg/hr.
For prophylaxis of Mendelson syndrome:
50 mg (2 mL) by I.M. or slow I.V. injection 45-60 minutes before induction of anaesthesia.
Children:
Use in children has not been evaluated.

Route of Administration:
For intramuscular and intravenous administration

Compatibilities:
Cautions for Usage:
Dilution: Vesyca Injection has been shown to be compatible with the following I.V. 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. Although compatibility studies have only been undertaken in polyvinyl chloride infusion bags (in glass for Sodium Bicarbonate BP) and a polyvinyl administration set it is considered that adequate stability would also be conferred by use of a polyethylene infusion bag. All unused admixtures of Vesyca Injection with infusion fluids should be discarded 24 hrs after preparation.

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Contraindication(s):
Contraindicated in patients who have known hypersensitivity to ranitidine.

Precaution(s) / Warning(s):
1. The possibility of malignancy should be excluded before commencement of therapy in patients with gastric ulcer (and if indications include dyspepsia; patients of middle age and over with new or recently changed dyspeptic symptoms) as treatment with ranitidine may mask symptoms of gastric carcinoma and may therefore delay diagnosis of the condition.
2. Since ranitidine is excreted primarily through the kidney, dosage should be adjusted in patients with severe renal impairment and doses of 25 mg (1 mL) are recommended.
3. Regular supervision of patients who are taking NSAIDs concomitantly with ranitidine is recommended especially in the elderly and in those with a history of peptic ulcer.
4. Ranitidine may precipitate acute porphyric attacks, and therefore it should be avoided in patients with a history of acute porphyria.
5. Use of higher than recommended doses has been associated with rises in liver enzymes when treatment has been extended beyond 5 days.
6. Bradycardia in association with rapid administration of ranitidine injection has been reported rarely, usually in patients with factors predisposing to cardiac rhythm disturbances. Recommended rates of administration should not be exceeded.

As this preparation contains Benzyl Alcohol, its use should be avoided in children under two years of age. Not to be used in neonates.

Interaction with Other Medicaments:
Ranitidine does not affect cytochrome P450 to any great extent, and therefore is considered to have little effect on the metabolism of other drugs. The absorption of ranitidine is reported to be impaired by the concomitant administration of sucralfate (2 g). This effect is not seen if sucralfate is taken after an interval of 2 hours.

Pregnancy and Lactation:
Ranitidine crosses the placenta and is excreted in human breast milk. It should only be used during pregnancy and nursing if considered essential.

Side Effect(s) / Adverse Reaction(s):
Transient and reversible changes in liver function tests; hepatitis with or without jaundice; acute pancreatitis (rare); reversible blood count changes (leucopenia, thrombocytopenia); rare cases of agranulocytosis; hypersensitivity reactions (urticaria, angioneurotic oedema, fever, bronchospasm, hypotension, anaphylactic shock, chest pain); bradycardia, AV-block and asystole; headache; dizziness; reversible mental confusion, depression, hallucinations; reversible blurred vision; skin rash which includes erythema multiforme; musculoskeletal symptoms (arthralgia and myalgia).

Symptoms and Treatment for Overdosage, and Antidote(s):
Ranitidine is very specific in action and accordingly no particular problems are expected following overdosage with the drug. Up to 6 g/day has been administered without untoward effect. Symptomatic and supportive therapy should be given as appropriate. If need be, the drug may be removed from the plasma by haemodialysis.

Shelf-Life:
3 years from the date of manufacture.

Storage Condition(s):
Store at temperature below 30℃. Protect from light and moisture.

Product Description & Packing(s):
A clear colourless to light yellowish solution.
2 mL x 50 vials / Box

Manufacturer:
YUNG SHIN PHARMACEUTICAL IND. CO., LTD.
Taichung Youth Factory
No. 27, Kung Chiu Rd., Tachia, Taichung, Taiwan, R.O.C.

Importer and Product Registration Holder :
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