Only for the use of Medical Professional

Xantid®

Ranitidine

Presentation

Xantid® Tablets: Each tablet contains Ranitidine 150mg as Hydrochloride USP
Xantid®-hs Tablets: Each tablet contains Ranitidine 300m9 as Hydrochloride USP
Xantid® lnjection: Each 2ml contains 50mg Ranitidine as hydrochloride USP

Uses

Xantid®, Xantid®-hs and Xantid® injection are indicated for the treatment of duodenal ulcer and benign gastric ulcer, including that associated with non-steroidal anti-inflammatory agents. Xantid®, Xantid®-hs and Xantid® injection are also indicated for the treatment of postoperative ulcer, oesophageal reflux disease and Zollinger-Ellison Syndrome. Ranitidine treatment is beneficial for patients with chronic episodic dyspepsia, characterized by pain (epigastric of retrosternal), which is related to meals or disturbs sleep but is not associated with the preceding conditions. Xantid®, Xantid®-hs and Xantid® injection are indicated for conditions where reduction of gastric secretion and acid output is desirable; such as the prophylaxis of gastrointestinal haemorrhage from stress ulceration in seriously ill patients, the prophylaxis of recurrent hemorrhage in patients with bleeding peptic ulcers and before general anesthesia in patients considered to be at risk of acid aspiration (Mendelson's Syndrome); particularly obstetric patients during labour. Concomitant antacid may be given as needed for relief of pain.

Dosage and administration

Adults: The usual dosage is 150mg Xantid® twice daily, taken in the morning and evening. Alternatively, patients with duodenal ulceration gastric ulceration or oesophageal reflux disease may be treated with a single bed-time dose of 300mg Xantid®-hs. lt is not necessary to time the dose in relation to meals. ln most cases of duodenal ulcer, benign gastric ulcer and post-operative ulcer, healing occurs in 4 weeks. A further 4 weeks of treatment may be needed in those patients whose ulcers have not fully healed after the initial course of therapy.

ln ulcers following non-steroidal anti-inflammatory drugs therapy or associated with continued non- steroidal anti-inflammatory drugs, 8 weeks treatment may be necessary. In duodenal ulcer 300m9 twice daily for 4 weeks results in rapid healing than those at 4 weeks with Ranitidine 150mg twice daily or 300mg once at bed-time. The increased dose has not been associated with an increased incidence of unwanted effects. For patients with a history of recurrent ulcer or after a short-term therapy, maintenance treatment at a reduced dosage of 150m9 at bedtime is recommended.

ln the management of oesophageal reflux disease, the recommended course of treatment is either 150mg twice daily or 300mg at bedtime for up to 8 weeks. ln patients with severe

oesophagitis, and those who fail to respond to standard doses of Ranitidine, the dosage of Ranitidine may be increased to 300mg Xantid®-hs four times daily for up to 8 weeks. The increased dose has not been associated with an increased incidence of unwanted effects.

ln patients with Zollinger Ellison Syndrome, the starting dose is 150mg three times daily and this may be increased up to 6gm daily as necessary and these doses have been well toleraled. For patients with chronic episodic dyspepsia the recommended course of treatment is 150mg twice daily for up to 6 weeks. Anyone not responding or relapsing shortly afterwards should be investigated. In the prophylaxis of hemorrhage from stress ulceration in seriously ill patients or the prophylaxis of recurrent hemorrhage in patients bleeding from peptic ulceration, treatment with Xantid® 150mg twice daily may be used.

ln patients thought to be at risk of acid aspiration syndrome a dose of 150mg can be given 2 hours before induction of general anesthesia, and preferably also 150mg the previous evening.

ln obstetric patients at commencement of labor. Xantid® may be given followed by 150mg at 6 hourly intervals. Since gastric emptying and drug absorption are delayed during labor, it is recommended that any patient requiring emergency general anesthesia should be given, in addition, a non-particulate antacid (e.g. sodium citrate) prior to induction of anesthesia. The usual precautions to avoid acid aspjration should also be taken.

Children: Use of Ranitidine in children has not been fully evaluated in clinical studies. However, it has been used successfully in children aged 8 to 18 years in dose up to 150mg (2 mg/kg) twice daily. *Parenteral administration*: ln some hospitalized patients with pathological hypersecretory conditions or interactable duodenal ulcers, or in patients who are unable to take oral medication, Xantid® may be administered parenterally according to the following recommendations:
Intramuscular lnjection; 50mg (2ml) every 6 to 8 hours. (No dilution necessary.)
Intermittent Intravenous Injection :

a. Intermittent Bolus: 50mg (2ml) every 6 to 8 hours. Dilute Xantid® lnjection, 50mg, in 0.9% sodium chloride jnjection or other compatible lV solution to a concentration no greater thin 2.5 mg/ml (20 ml). Inject at a rate no greater than 4ml/min (5 minutes).
b. Intermittent lnfusion 50mg (2ml) every 6 to 8 hours. Dilute Xantid® injection, 50mg, in 5% dextrose injection or oiher compatible lV solution to a concentration no greater than 0.5 mg/ ml (100ml). Infuse at a rate no greater than 5 to 7 ml/ min (15 to 20 minutes). ln some patients it may be necessary to increase dosage. When this is necessary, the increases should be made by more frequent administration of the dose, but generally should not exceed 400 mg/ ml.

Continuous lntravenous Infuslon: Add Xantid® injection to 5% dextrose injection Or other compatible lV sotution . Deliver at a rate of 6.25 .mg/h (e.g.,150mg [6 ml] of Xantid® injection in 250ml of 5% dextrose injection at 10.7 ml/h).

Contra-indications, warnings, etc.
Contra-indications: Known hypersensitivity to the drug.

Precautions: Histamine H_2-antagonist may mask symptoms associated with carcinoma of the stomach and may therefore delay diagnosis of the condition. As Ranitidine is excreted through kidney, in severe renal impairment plasma level of the drug increases. Therefore, it is recommended that the dosage of Ranitidine in such patients be 150mg at night for 4 to 8 weeks. lf an ulcer has not healed after treatment the standard dosage regimen of 150mg twice daily be instituted, followed if need be, by maintenance treatment at 150mg at night. Regular supervision of patients with peptic ulcer and on non-steroidal anti- inflammatory drugs is recommended, especially in elderly. Ranitidine crosses the placenta but therapeutic doses administered to obstetric patients in-labor or undergoing cesarean section have been without any adverse effect on labour, delivery or subsequent neonatal progress. Ranitidine is also excreted in human breast milk. Like other drugs Ranitidine should only be used during pregnancy and lactation if essential.

Side effects: ln clinical trials or in the routine management of patients treated with Ranitidine the following events have been reported. The relationship to Ranitidine therapy has not been established in many cases. Transient and reversible changes in liver function tests can occur. Occasionally hepatitis (hepatocellular, hepatocanalicular or mixed) with or without jaundice has been reported. These were usualty reversible. In rare occasions reversible leucopenia and thrombocytopenia have been observed in patients.

Rare cases of agranulocytosis or of pancytopenia, sometimes with marrow hyperplasia, or aplasia have been reported. Hypersensitivity reactions (urticaria, angioneurotic oedema. fever, bronchospasm, hypotension, anaphylactic shock) have been seen rarely following the administration of Ranitidine. These reactions have occasionally occured after a single dose.

As with other H_2-receptor antagonists, there have been rare reports of bradycardia and A-V block. Headache, sometimes severe, and dizziness have been reported in a very small oroportion of patients. Rare cases of reversible mental confusion and hallucinations have been reported predominantly in severely ill and elderly patients. Skin rash has been rarely reported.

Ranitidine does not interfere significantly with endocrine or gonadal function. Few reports of breast symptoms (swelling and/or discomfort; in men taking Ranitidine have been reported; some cases have resolved on continued Ranitidine treatment. Discontinuation of therapy may be necessary in order to establish the underlying cause.

Use in elderly patients: In clinical trial the ulcer healing rates have been found similar in patients age 65 and over with those in younger patients. Additionally, there was no difference in the incidence of adverse effects.

Overdosage: Ranitidine is very specific in action and accordingly no particular problems are expected following overdosage with the-drug. Symptomatic and supportive therapy should be given as appropriate. If required, the drug may be removed from the plasma by haemodiaiysis.

Pharmaceutical precautions
Store in a cool and dry place. protect from light.

Package quantities
Xantid® Tablets: Carton of 150 tablets in blister.
Xantid®-hs Tablets: Carton of 100 tablets in blister.
Xantid® Injection: Carton of 10 ampoules.

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