Package Leaflet: Information for the User

Zantac 25 mg/ml Solution for Injection/Infusion
ranitidine (as ranitidine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1 What Zantac is and what it is used for

Zantac contains a medicine called ranitidine. This belongs to a group of medicines called H_2-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) Zantac is used to:
- treat ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- manage problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as ‘indigestion’, ‘dyspepsia’ or ‘heartburn’
- prevent acid coming up from the stomach while under anaesthetic during an operation
- prevent bleeding from the stomach and part of the gut it empties into (the duodenum)
- treat Zollinger-Ellison syndrome – a condition in which there is increased production of the hormone gastrin

For children (6 months to 18 years) Zantac is used to:
- treat ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- treat and stop problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as “indigestion”, “dyspepsia” or “heartburn”

2 What you need to know before you have Zantac

Do not have Zantac if:
- you are allergic (hypersensitive) to ranitidine or any of the other ingredients of Zantac (listed in Section 6).

If you are not sure, talk to your doctor, pharmacist or nurse before having Zantac.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Zantac if:

- you have stomach cancer
- you have kidney problems. You will need to have a different amount of Zantac
- you have had stomach ulcers before
- you have a history of heart trouble
- you have a rare condition called acute porphyria
- you are a smoker
- you suffer from long-term lung disease, diabetes, are over 65 years or are unable to resist infection as you may be at increased risk of getting a serious chest infection (pneumonia); symptoms include fever, cough and breathlessness.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before having this medicine.

Use in Infants (under 6 months):
Zantac is not recommended in infants under 6 months of age.

Other medicines and Zantac
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Zantac can affect the way some other medicines work. Also some other medicines can affect the way Zantac works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:
- lidocaine, a local anaesthetic
- propranolol, procainamide or n-acetylprocainamide, for heart problems
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy
- theophylline, for breathing problems (asthma)
- Certain Anticoagulants (such as Warfarin), for thinning your blood, as Zantac may alter the effect of these medicines
- glipizide, for lowering blood glucose
- atazanavir or delaviridine, for treating HIV infection
- triazolam, for insomnia
- gefitnib, for lung cancer
- ketoconazole, an anti fungal medicine, sometimes used for treating thrush.
- Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking Zantac before your operation in case he or she wants to give you Midazolam.
- Sucralfate, for treating stomach ulcers.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before having Zantac.

Pregnancy and breast-feeding
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Zantac is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients of Zantac
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3 How to have Zantac Solution for Injection/Infusion

You will never be expected to give yourself this medicine. It will always be given to you by a person who is trained to do so.

Having this medicine
Zantac Injection will be given to you either:
- as a single injection into a muscle
- as a slow infusion into a vein. This is where the drug is slowly given to you over a few minutes
- as a continuous infusion into a vein. This is where the drug is slowly given to you over a few hours.

The usual dose for an adult (including the elderly) and adolescents (12 years and older) is 50 mg every 6 to 8 hours, as a single injection into a muscle.

Different doses may also be given to you as a slow infusion or continuous infusion, depending on what condition you are being treated for.

Use in Children and infants (6 months to 11 years):
Your doctor will give Zantac by a slow injection into a vein. The maximum dose is 50 mg every 6 or 8 hours. It is usually only given while your child is unable to take Zantac by mouth.

If you are given more Zantac than you should
Your doctor or nurse will give you Zantac injection so it is unlikely that you will receive too much. If you think you have been given too much or have missed a dose, tell your doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, the medicine can cause side effects, although not everybody gets them.

Conditions you need to look out for

Severe allergic reaction: These are rare in people taking Zantac. Signs include:
- raised and itchy rash (*hives*)
- swelling, sometimes of the face or mouth (*angioedema*)
- chest pain, shortness of breath, unexplained fever, wheezing or difficulty in breathing
- feeling faint, especially when standing up
- collapse

Contact a doctor immediately if you get any of these symptoms. Stop taking Zantac.

Serious skin reactions: these are very rare in people taking Zantac. Signs include:
- Skin rash, which may blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge).

Contact a doctor immediately if you get any of these symptoms. Stop taking Zantac.

Uncommon side effects
These may affect **up to 1 in 100** people
- Abdominal pain
- Constipation
- Nausea

Rare side effects
These may affect **up to 1 in 1,000** people:
- Allergic reactions
- Skin rash
- Elevation of Creatinine
- Changes to liver function

Very rare side effects
These may affect **up to 1 in 10,000** people:
- inflammation of blood vessels (*vasculitis*)
- inflammation of the pancreas (*pancreatitis*)
- inflammation of the liver (*hepatitis*), sometimes with yellowing of the whites of the eyes or skin (*jaundice*)
- inflammation in the kidney (*interstitial nephritis*)
- slow, fast or irregular heartbeat
- diarrhoea
- feeling confused, depressed, or seeing or hearing things that are not really there (*hallucinations*)
- joint or muscle pain, or uncontrolled movement
- headache, dizziness, blurred vision
- unusual hair loss or thinning (*alopecia*)
- unable to get or maintain an erection (*impotence*)
- unusual secretion of breast milk or breast enlargement in men.
- low levels of white blood cells
- decrease in number of blood platelets (cells that help blood to clot)
- decrease in number of all types of blood cells

Not known (frequency cannot be estimated from the available data)
- shortness of breath

Speak to your doctor if you experience unexplained bruising, recurrent infection, tiredness or fainting.

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax +353 1 6762517. Website www.hpra.ie; email: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Zantac

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
- Do not store above 25°C and discard 24 hours after preparation.
- Keep ampoule in the outer carton to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of pack and other information

What Zantac contains:
- The active substance is ranitidine (as the hydrochloride).
- Each ampoule contains ranitidine hydrochloride equivalent to 50 mg ranitidine in 2 ml i.e. 25 mg/ml.
- The other ingredients are sodium chloride, potassium dihydrogen phosphate, disodium phosphate anhydrous and water for injections.

What Zantac looks like and contents of the pack
Zantac Injection is a clear, colourless to pale yellow liquid. You shouldn't be able to see any particles in it.

Cartons contain five 2 ml glass ampoules.

For single use only. Discard any unused content.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24.
Manufacturer: GlaxoSmithKline Manufacturing S.p.A., 43056 San Polo di Torrile, Parma, Italy

The information provided applies only to Zantac 25 mg/ml Solution for Injection/Infusion

This leaflet was last revised in August 2018

Package leaflet: Information for Healthcare Professionals

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ranitidine (as ranitidine hydrochloride)

Please refer to the Summary of Product Characteristics (SPC) for further details on this product.

Qualitative and Quantitative Composition

Each ampoule contains ranitidine hydrochloride equivalent to 50 mg ranitidine in 2 ml i.e. 25 mg/ml.
Each ampoule also contains 2.9 mg (0.09 mmol) of sodium and 0.6 mg (0.015 mmol) of potassium.

Pharmaceutical Form

Solution for Injection/Infusion.
A sterile, clear colourless to pale yellow aqueous solution.

Posology and Method of Administration

Adults (including elderly)/adolescents (12 years and over)

Zantac Injection may be given as a slow (over 2 minutes) intravenous injection of 50 mg, diluted to a volume of 20 ml, every 6 to 8 hours as required until oral therapy can be introduced; or as an intermittent intravenous infusion at 25 mg per hour for two hours; repeated at 6 to 8 hour intervals, or as an intramuscular injection of 50 mg every 6 to 8 hours.
In the prophylaxis of upper gastro-intestinal haemorrhage 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 the prophylaxis of haemorrhage from stress ulceration in seriously ill patients or the prophylaxis of recurrent haemorrhage in patients bleeding from peptic ulceration, parenteral administration may be continued until oral feeding commences. Patients considered to be still at risk may then be treated with Zantac Tablets 150 mg twice daily.
In patients considered to be at risk of developing acid aspiration (Mendelson's) syndrome, Zantac Injection 50 mg may be given intramuscularly or by slow intravenous injection 45 to 60 minutes before induction of general anaesthesia.

Children/infants (6 months to 11 years)

See SPC section 5.2 Pharmacokinetic properties – Special patient populations.
Zantac Injection may be given as a slow (over 2 minutes) IV injection up to a maximum of 50 mg every 6 to 8 hours.

Peptic ulcer acute treatment and gastro-oesophageal reflux
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, Zantac Injection may be administered at doses that have been shown to be effective for these diseases in adults and effective for acid suppression in critically ill children. The initial dose (2.0 mg/kg or 2.5 mg/kg, maximum 50 mg) may be administered as a slow intravenous infusion over 10 minutes, either with a syringe pump 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.

Neonates (under 1 month)
See SPC section 5.2 Pharmacokinetic properties – Special patient populations.

Renal Impairment
Accumulation of ranitidine with resulting elevated plasma concentrations will occur in patients with severe renal impairment (creatinine clearance less than 50 ml/min). It is recommended in such patients that Zantac be administered in doses of 25 mg.

Overdose

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

Reconstitution and dilution of Zantac 25 mg/ml Solution for Injection/Infusion

This medicinal product must not be mixed with other medicinal products except those listed below.

Zantac Injection is compatible with the following intravenous infusion fluids:
- 0.9% Sodium Chloride BP
- 5% Dextrose BP
- 0.18% Sodium Chloride and 4% Dextrose BP
- 4.2% Sodium Bicarbonate BP
- Hartmann's Solution.

Although compatibility studies have only been undertaken in polyvinyl chloride infusion bags (in glass for Sodium Bicarbonate BP) and polyvinyl chloride administration sets, it is considered that adequate stability would be conferred by use of a polyethylene infusion bag.

Shelf Life

3 years
All admixtures of Zantac injection with compatible infusion fluids (as listed in section 6.6) should be stored below 25°C and discarded 24 hours after preparation.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the

responsibility of the user. Dilution should take place in controlled and validated aseptic conditions.

Special Precautions for Storage

Do not store above 25°C. Keep ampoule in the outer carton in order to protect from light. Do not autoclave.

Instructions for Use/Handling

For single use only. Discard any unused content.

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