Information for Healthcare Professionals

Zantac® Injection 50 mg/2 ml
ranitidine hydrochloride

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

Qualitative and Quantitative Composition
Ranitidine hydrochloride HSE 56 mg/2 ml equivalent to ranitidine 50 mg/2 ml.

Each ampoule contains 2.9 mg (0.09 mmol) of sodium and 0.6 mg (0.015 mmol) of potassium.

For the full list of excipients, see SPC section 6.1.

Pharmaceutical Form
Injection (Aqueous solution)
A clear colourless to pale yellow liquid, practically free from particles

Posology and method of administration
(See SPC section 5.2 Pharmacokinetic properties – Other special populations.)

Posology
- Adults (including elderly)/adolescents (12 years and over)
  Zantac Injection may be given as a slow (over 2 minutes) intravenous injection up to a maximum of 50 mg, after dilution to a volume of 20 ml per 50 mg dose, which may be repeated every 6 to 8 hours; or as an intermittent intravenous infusion at a rate of 25 mg per hour for two hours; the infusion may be repeated at 6 to 8 hour intervals, or as an intramuscular injection of 50 mg (2 ml) every 6 to 8 hours.
  Prophylaxis of haemorrhage from stress ulceration or recurrent haemorrhage:
  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 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.
  Prophylaxis of Mendleson's syndrome:
  In patients considered to be at risk of developing acid aspiration 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 – Other special populations.)
  Zantac Injection may be given as a slow (over 2 minutes) i.v. 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 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 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 – Other special populations.)

**Patients with 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). Accordingly, it is recommended in such patients that ranitidine be administered in doses of 25 mg.

- Method of administration
  Intravenous or intramuscular injection.
  For instructions on dilution of the medicinal product before administration, see SPC section 6.6.

**Shelf life**
36 months unopened.

**Special precautions for storage**
Store below 25°C, protect from light.
Zantac Injection should not be autoclaved.

**Special precautions for disposal and other handling**
Zantac Injection has been shown to be 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.

All unused admixtures of Zantac Injection with infusion fluids should be discarded 24 hours after preparation.
Although compatibility studies have only been undertaken in polyvinyl chloride infusion bags (in glass for Sodium Bicarbonate BP) and a polyvinyl chloride administration set it is considered that adequate stability would be conferred by the use of a polyethylene infusion bag.

Information for Healthcare Professionals. This leaflet was last revised in February 2015

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Zantac® Injection 50 mg/2 ml
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
2. What you need to know before you have Zantac
3. How to have Zantac Injection
4. Possible side effects
5. How to store Zantac
6. Contents of the pack and other information

1. What Zantac is and what it is used for

Zantac contains a medicine called ranitidine. This belongs to a group of medicines called H₂-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) Zantac is used to:
- heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- stop ulcers from bleeding
- improve 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’
- stop acid coming up from the stomach while under anaesthetic during an operation.

For children (6 months to 18 years) Zantac is used to:
- heal ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- heal 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 to ranitidine or any of the other ingredients of this medicine (listed in section 6).

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

Warnings and precautions
Check with your doctor or pharmacist before having your medicine 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 over 65 years old
• you have lung disease
• you are diabetic
• you have any problems with your immune system.

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

Other medicines and Zantac
Tell your doctor or pharmacist 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)
• warfarin, for thinning your blood
• glipizide, for lowering blood glucose
• atazanavir or delavirdine, for treating HIV infection
• triazolam, for insomnia
• gefitinib, 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.

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

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before having this medicine. You should not take this medicine unless your doctor advises it is essential.

Zantac contains sodium
Zantac Injection contains less than 23 mg of sodium and is therefore essentially sodium-free.

Zantac Injection contains less than 39 mg (1mmol) of potassium and is therefore essentially potassium-free.

3 How to have Zantac Injection

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.

### 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Stop taking Zantac and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reactions, the signs may include:
  - rash, itching or hives on the skin
  - swelling of your face, lips, tongue or other parts of the body
  - chest pain, shortness of breath, wheezing or having trouble breathing
  - unexplained fever and feeling faint, especially when standing up
- kidney problems, which can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood tests
- severe stomach pain, this may be a sign of something called ‘pancreatitis’
- a slow or irregular heartbeat

Check with your doctor at your next visit if you notice any of the following:

**Uncommon** (may affect up to 1 in 100 people)

- stomach pain
- constipation
- feeling sick (nausea)

**Rare** (may affect up to 1 in 1,000 people)

- skin rash
Rare side effects that may show up in blood tests:
- increase of serum creatinine in the blood (kidney function test)
- changes to liver function

Check with your doctor as soon as possible if you notice any of the following:

**Very rare** (may affect up to 1 in 10,000 people)
- there can be changes in the level of certain substances in your blood. This can lead to you feeling unusually tired or short of breath and being more likely to bruise or get an infection
- feeling depressed, confused, seeing or hearing unexplained things (hallucinations)
- headache (sometimes severe)
- feeling dizzy or having blurred vision
- your joints or muscles are painful or swollen or you cannot control their movement
- your small blood vessels can become swollen (known as ‘vasculitis’). Signs of this can include: a rash, swollen joints or kidney problems
- your liver can become swollen. This can lead to: nausea (feeling sick) or vomiting (being sick), loss of appetite or generally feeling unwell, itching, fever, yellowing of the skin and eyes or dark coloured urine
- flushing or marks on your skin that look like targets
- unexplained hair loss
- diarrhoea
- impotence
- breast tenderness and/or breast enlargement
- breast discharge
- awareness of the heart beat and/or increased heart rate

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

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

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. The expiry date refers to the last day of that month.
- Store below 25°C
- 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 the pack and other information

What Zantac contains
- The active substance is ranitidine (as the hydrochloride) 50 mg
- The other ingredients are sodium chloride, potassium dihydrogen orthophosphate, disodium hydrogen orthophosphate 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.

Marketing Authorisation Holder and Manufacturer
Product licence held by Glaxo Wellcome UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.
Manufactured by GlaxoSmithKline Manufacturing S.p.A., San Polo di Torrile, Parma, Italy.

The information provided applies only to Zantac Injection 50 mg/2 ml

Other sources of information
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Zantac Injection 50 mg/2 ml
Reference number 10949/0109

This is a service provided by the Royal National Institute of Blind People.

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