Ranitidine 50mg/2ml Solution for Injection and Infusion
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 or nurse.
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of this medicine is Ranitidine 50mg/2ml Solution for Injection and Infusion (referred to as Ranitidine Injection throughout this leaflet).

What is in this leaflet:
1. What Ranitidine Injection is and what it is used for
2. What you need to know before you have Ranitidine Injection
3. How to have Ranitidine Injection
4. Possible side effects
5. How to store Ranitidine Injection
6. Contents of the pack and other information

1. WHAT RANITIDINE INJECTION IS AND WHAT IT IS USED FOR

Ranitidine Injection is a solution for injection or infusion into a vein, or injection into a muscle. It contains ranitidine as the active substance. Ranitidine is one of a group of medicines called H₂-antagonists that lowers the amount of acid in your stomach.

It is used in adults (including the elderly) to:
• Heal ulcers in the stomach or the part of the gut that it empties into (the duodenum) (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as ‘indigestion’, ‘dyspepsia’ or ‘heartburn’
• Stop ulcers from bleeding
• Stop acid coming up from the stomach while under anaesthetic during an operation.

It is used in children (6 months to 18 years) to:
• Heal ulcers in the stomach or the part of the gut that it empties into (the duodenum) (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 RANITIDINE INJECTION

Do not have Ranitidine Injection if:
• You are allergic to ranitidine or to any of the other ingredients in this medicine (listed in Section 6 of this leaflet).
• If you are not sure to talk to your doctor or pharmacist before having Ranitidine Injection.

Warnings and precautions
Taking your doctor or pharmacist before having Ranitidine Injection if:
• You have stomach cancer
• You have kidney problems. You will need to have a different amount of Ranitidine Injection.
• You have a heart problem or history of heart trouble
• You have a rare condition called acute porphyria
• You have had stomach ulcers before
• You are over 65 years old
• You have lung disease
• You are diabetic
• You have problems with your immune system

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

Other medicines and Ranitidine Injection
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines that you buy without a prescription and herbal medicines. This is because ranitidine can affect the way some other medicines work. Also some other medicines can affect the way ranitidine works. In particular tell your doctor or pharmacist if you are taking any of the following medicines:
• lidocaine, a local anaesthetic
• anticoagulants (such as warfarin), used to thin the blood
• propranolol, procaïnamide or n-acetylcarnosine, for heart problems
• diazepam, for worry or anxiety problems
• phenytoin, for epilepsy
• theophylline, for breathing problems (asthma)
• glipizide, for lowering blood glucose
• atazanavir or delavirdine, for treating HIV infection
• gefinib for lung cancer
• ketocanozole for fungal infections or thrush
• triazolam for insomnia.

Midazolam may also be given before an operation. Tell your doctor you are taking ranitidine before you have an operation in case he or she wants to give you midazolam.

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

Pregnancy and breast-feeding
If you are pregnant, might become pregnant or breast-feeding you should not be given this medicine unless your doctor advises it is essential. Ask your doctor, pharmacist or nurse for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines
Ranitidine Injection is unlikely to affect your ability to drive or operate machinery.

Ranitidine Injection contains Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per 50 mg, i.e. essentially sodium-free.

The following information is intended for medical or healthcare professionals only:

Ranitidine 50mg/2ml Solution for Injection and Infusion
Please read this information carefully before giving Ranitidine 50mg/2ml Solution for Injection and Infusion (referred to as Ranitidine Injection throughout this leaflet). Please refer to the Summary of Product Characteristics for further details on this product.

Presentation
Each 2ml ampoule of Ranitidine Injection contains 50mg of ranitidine as ranitidine hydrochloride. Product provided in amber glass ampoules, 5 ampoules in a carton.

Pharmaceutical Form
Solution for Injection and Infusion
Clear, colourless solution

Indications
Ranitidine Injection is indicated for the treatment of duodenal ulcer, benign gastric ulcer, post-operative ulcer, and of Zollinger-Ellison Syndrome.

In the management of conditions where reduction of gastric secretion and acid output is desirable, such as reflux oesophagitis.

As prophylaxis against:
• gastrointestinal 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 orally with Ranitidine tablets 150 mg twice daily.
• an intermittent intravenous infusion at a rate of 25 mg per hour for two hours, the infusion may be repeated at 6 to 8 hours intervals; or
• an intramuscular injection of 50 mg (2ml) every 6 to 8 hours.

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 orally with Ranitidine 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 Mendelsohn’s syndrome:
In patients considered to be at risk of developing acid aspiration, Ranitidine Injection may be given intramuscularly or by slow intravenous injection 45 to 60 minutes before induction of general anaesthesia.

Dosage and Method of Administration
See SPC section 5.2 Pharmacokinetic Properties - Special Patient Populations.

Recommended rates of administration should not be exceeded as Bradyardia in association with rapid administration of ranitidine has been reported rarely.

Adults (including elderly) and adolescents (12 years and older)
Ranitidine Injection may be given as:
• a slow (over two 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
• an intermittent intravenous infusion at a rate of 25 mg per hour for two hours, the infusion may be repeated at 6 to 8 hours intervals; or
• an intramuscular injection of 50 mg (2ml) every 6 to 8 hours.

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 orally with Ranitidine 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.
3. HOW TO HAVE RANITIDINE INJECTION

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

Your doctor will decide the correct dose of Ranitidine injection for you.

Adults (including the elderly) and adolescents (12 years and older):

This can be given by the doctor or nurse in one of three ways:

- As a single injection into a muscle
- As a slow infusion into a vein
- As a continuous infusion into a vein

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.

Children and infants (6 months to 11 years):
The dose will be given by a slow injection into a vein. The maximum dose is 50mg every 6 or 8 hours. It is usually only given if your child is unable to take ranitidine by mouth.

Kidney impairment: If any of these are not working properly your doctor may give you a lower dose.

Your doctor or nurse will give you Ranitidine injection so it is unlikely that you will receive too much. If you have the impression that you have received too much Ranitidine injection speak to your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ranitidine Injection can cause side effects, although not everybody gets them.

A few people can be allergic to some medicines. If any of the following happen, tell your doctor or nurse immediately as you may need urgent medical attention:

- Severe itching of the skin, rash or hives on the skin
- Swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat which may cause difficulty in swallowing or breathing.
- Swelling on other parts of the body
- Chest pain, shortness of breath, wheezing or having trouble breathing
- Unusual 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 pains, this may be a sign of something called peritonitis
- A slow or irregular heartbeat
- Collapse

You may have had a serious allergic reaction to Ranitidine Injection.

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

Uncommon side effects (less than 1 in 100)

- Stomach pain
- Constipation
- Feeling sick (nausea).

Rare side effects that may show up in blood tests:

- Increase of serum creatinine in blood (kidney function test)
- Changes to liver function

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

Very rare side effects (less than 1 in 10,000)

- Depression
- Confusion, hallucinations (seeing or hearing unexplained things)
- Blood changes that may result in unusual tiredness, shorness of breath, being more likely to get infections, bruising more easily
- Uncontrolled movements
- Your small blood vessels can become swollen (known as vasculitis) this could include: a rash, swollen joints or kidney problems
- Headaches (sometimes severe)
- Diarrhoea
- Feeling dizzy or having blurred vision
- 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 dark coloured urine.
- Red blotsches or lumps on the skin that may look like targets, unexplained hair loss
- Your joints or muscles are painful and swollen
- If you have sexual impotence (this is normally reversible), tenderness of the breast, breast discharge and/or breast enlargement.

Reporting of side effects

If you have any side effects talk to your doctor or nurse.

This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via:

OECD: OECD Pharmacovigilance, Errolfort Terrace, IRL - Dublin 2; Tel: +353 1 6764791; Fax: +353 1 6762517.
Website: www.hpra.ie, E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RANITIDINE INJECTION

Do not store above 25°C

Keep ampoules in the carton to protect them from light. Keep ampoule out of the sight and reach of children. Ranitidine Injection should not be used after the expiry date which is stated on the ampoule and carton. The expiry date refers to the last day of that month.

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. FURTHER INFORMATION

What Ranitidine Injection contains

The active substance is ranitidine. One 2ml ampoule contains 50mg of ranitidine as ranitidine hydrochloride. Other ingredients are sodium chloride, potassium dihydrogen phosphate, disodium hydrogen phosphate dihydrate,

What Ranitidine Injection looks like and contents of the pack

Ranitidine Injection is a clear, colourless liquid in amber glass ampoules. Each carton of Ranitidine Injection contains 5 ampoules.

Marketing Authorisation Holders

Alliance Pharmaceuticals Limited, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

Manufacturers: Kleva S A, 189 Parnithos Avenue, 136 71 Acharna, Athens, Greece.

This leaflet was last revised in December 2014

Alliance and associated devices are registered trademarks of Alliance Pharmaceuticals Limited

© Alliance Pharmaceuticals Limited 2014