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.

• If you have had the medicine before, you may not need to read it again.
• If you have any further questions, ask your doctor or nurse.
• 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. Possible side effects.

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 and stop ulcers of the stomach or duodenum (the stomach empties into this part of the intestine)
• 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 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)
• 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 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 talk to your doctor or pharmacist before having Ranitidine Injection.

Warnings and precautions
Talk to your doctor or pharmacist before having Ranitidine Injection:
• if you have stomach cancer
• if you have kidney problems. You will need to have a different amount of Ranitidine Injection.

• if you have a heart problem or a history of heart trouble
• if you have a rare condition called acute porphyria
• if you have had stomach ulcers before
• if you are over 65 years old
• if you have lung disease
• if you are diabetic
• if 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, have recently taken or are going to 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, procainamide or α-acetylsalicylic acid, for heart problems
• diazepam, for worry or anxiety problems
• phenytoin, for epilepsy
• theophylline, for breathing problems (asthma)
• glipizide, for lowering blood glucose
• atazanavir or darunavir, for treating HIV infection
• gefitinib for lung cancer
• ketoconazole for fungal infections or thrush
• trizolam 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 Ranitidine Injection.

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 and Potassium

Ranitidine Injection contains less than 1 mmol sodium (23 mg) per 50 mg, i.e. essentially sodium-free.
Ranitidine Injection contains less than 1mmol potassium (39 mg) per 50mg, i.e. essentially potassium-free.

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:

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

Dosage and Method of Administration

See SPC section 5.2
Pharmacokinetic Properties - Special Patient Populations.

Recommended rates of administration should not be exceeded as bradycardia 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 8 to 12 hours
• 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
• as an intramuscular injection of 50 mg (2ml) every 6 to 8 hours.

In the prophyaxis of haemorrhage from stress ulceration in seriously ill patients or the prophyaxis of recurrent haemorrhage in patients bleeding from one or more sites, 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 Menetrier’s disease

In patients considered to be controlled by acid production reduction. Ranitidine Injection 50 mg may be given intramuscularly or by slow intravenous injection 45 to 60 minutes before induction of general anaesthesia.
• 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 recommended 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 calculated according to body weight, age, and the amount of time the drug will be given. 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 disease: if your kidneys 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 think that the effect of Ranitidine Injection is too strong or too weak or you have missed a dose, talk to your doctor or nurse.

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

### 4. POSSIBLE SIDE EFFECTS

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

#### Serious side effects

If any of the following happen, tell your doctor or nurse immediately as you are showing signs of a serious allergic reaction:

- Severe itching of the skin, rash or hives on the skin
- Allergic reactions, the signs may include:
  - 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 difficulties in swallowing or breathing.
  - Swelling on other parts of the body
  - Chest pain, shortness of breath, wheezing or having trouble breathing
- Unexpected 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

#### Rare side effects that may show up in blood tests:

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

#### Other side effects

- Constipation
- Stomach pain
- Uncommon: may affect up to 1 in 100 people

#### Other side effects

- Collapse

#### Allergic reactions, the signs may include:

- Diarrhoea
- Feeling dizzy or having blurred vision
- Palpitations, which 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
- Red blotches or lumps on the skin that may look like targets, unexplained hair loss
- Your joints or muscles are painful and swollen
- If you are a man, sexual impotence (this is normally reversible), tenderness of the breast, breast discharge and/or breast enlargement.

### Reporting of side effects

If you get any possible 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:

- **UK:** The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
- **IE:** HPR Pharma Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: *+353 1 6764971*, Fax: *+353 1 6762617*.

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 25ºC.

Keep ampoules in the carton to protect them from light. Keep this medicine out of the sight and reach of children.

### 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, Water for injections.

#### 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 Holder

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

#### Marketing Authorisation

Manufacturers: Kleva S A, 189 Parnithos Avenue, 136 75 Achamia, Athens, Greece.

This leaflet was last revised in May 2016

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### Pharmacological Information

**Pharmacokinetic Properties - Special Patient Populations.**

- **Children and infants (6 months and above):** limited pharmacokinetic data show that the plasma clearance of ranitidine appears to be related to the estimated glomerular filtration rate in the neonates.
- **Patients over 50 years of age:** In patients over 50 years of age, half-life is prolonged (1.5-8.2 ml/min/kg) and the half-life increased in the new-born. Clearance of ranitidine appeared to be related to the estimated glomerular filtration rate in the neonates.
- **Neonates (under 1 month):** limited pharmacokinetic data from term babies undergoing treatment with Extracorporeal Membrane Oxygenation (ECMO) suggests that plasma clearance following i.v. administration may be reduced (1.5-2.2 ml/min/kg) and the half-life increased in the newborn. Clearance of ranitidine appeared to be related to the estimated glomerular filtration rate in the neonates.
- **Pharmacokinetic - Special Patient Populations.**

#### Incompatibilities:

This medicinal product must not be mixed with other medicinal products except with those listed below (see Instructions for Use and Handling).

- Sodium Chloride 0.9% w/v
- Dextrose 5% w/v
- Sodium Chloride 0.9% w/v
- Potassium Hydrogen Phosphate 0.55% w/v
- Sodium Chloride 0.9% w/v
- Sodium Chloride 0.9% w/v
- hydrogen phosphate dihydrate, Water for injections.

#### Instructions for Use and Handling: Ranitidine Injection has been shown to be compatible with the following intravenous infusion fluids:

- Sodium Chloride 0.9% w/v
- Dextrose 5% w/v
- Sodium Chloride 0.18% w/v and Dextrose 4% w/v
- Sodium Bicarbonate 4.2% w/v

#### Hartmann’s solution:

- This leaflet was last revised in May 2016

### Alliance

**Website:** www.hpra.ie, **E-mail:** medsafety@hpra.ie.