

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### **Ranitidine 25mg/ml Solution for Injection** Ranitidine hydrochloride

**Read all of this leaflet carefully before you start using 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 or pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Ranitidine 25mg/ml Solution for Injection but will be referred to as 'Ranitidine Injection' throughout the remainder of 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 use Ranitidine Injection
3. How to use 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 into a muscle or infusion into a vein. It contains ranitidine as the active ingredient. Ranitidine Injection belongs to a group of medicines called histamine H2 antagonists, which reduce the amount of acid in your stomach.

##### **For adults (including older people) Ranitidine is used to:**

- treat 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) Ranitidine 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.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE RANITIDINE INJECTION**

##### **Do not use Ranitidine Injection**

- if you are allergic to Ranitidine or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

**Talk to your doctor or pharmacist or nurse before you are given Ranitidine Injection if:**

- your kidneys are not working properly
- you have a rare illness called porphyria

- you are pregnant or think you may be pregnant
- you are breast-feeding
- you have heart rhythm problems, or a history of heart trouble
- you have had a ulcer in your stomach before
- you have a breathing problem or lung disease
- you have weak immune system
- you suffer from diabetes
- you have stomach cancer
- you are elderly (over the age of 65 years old)
- you experience unintentional weight loss associated with acid indigestion

### **Other medicines and Ranitidine Injection**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines such as:

- warfarin, for thinning your blood
- glipizide, for lowering blood sugar levels
- lidocaine, a local anaesthetic
- propranolol, procainamide or N-acetylprocainamide, for heart problems
- diazepam, for worry or anxiety problems
- phenytoin, for epilepsy (fits)
- theophylline, for breathing problems (asthma)
- atazanavir or delaviridine, for treating HIV infection
- triazolam, for sleep problems
- gefitinib, for lung cancer
- ketoconazole, to treat fungal infections such as thrush
- midazolam or triazolam, to help with sleeping problems. Midazolam is a medicine that may be given to you (by your doctor) just before you have an operation.

### **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 you are given this medicine.

As with other medicines, it is not recommended that Ranitidine Injection be used during pregnancy or breast feeding unless absolutely necessary.

### **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 1mmol each of sodium and potassium per ampoule (2ml) i.e. essentially sodium & potassium free.*

## **3. HOW TO USE RANITIDINE INJECTION**

This medicine will be given by your doctor or nurse in one of the following ways:

- 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.

### **Adults (including older people) and adolescents (12 years and over):**

The recommended dose is 50 mg every 6 to 8 hours, as a single injection into a muscle or as a slow injection or an intermittent infusion into a vein.

#### **For slow injection into the vein**

When administered slowly into the vein, the medicine is first diluted to a volume of 20ml and then given over a period of 2 minutes which may be repeated every 6 to 8 hours.

#### **For intermittent infusion into the vein**

25mg of the injection is directly infused into a vein each hour for 2 hours and may be repeated every 6-8 hours.

Different doses may also be given to you in the muscle or as a slow infusion or continuous infusion, depending on what condition you are being treated for. Your doctor will advise you.

#### **Patients with stomach disorders**

If you are receiving Ranitidine injection to prevent bleeding stress ulcers resulting from being seriously ill, or recurrently bleeding peptic ulcers, the injections may be continued until you are able to feed orally again.

For the prevention of bleeding from ulcers in the stomach and intestine in seriously ill patients, the treatment is initiated with a dose of 50mg of Ranitidine injected slowly into a vein followed by a continuous infusion of 0.125-0.25mg/kg/hr.

You may be given Ranitidine either in the muscle or by intravenous injection 45 -60 minutes before you receive general anaesthesia if it is suspected that you may develop acid aspiration syndrome (symptoms of laboured breathing while unconscious and having/or suspected to have vomited).

#### **Older people**

Normal dosage is recommended except for elderly patients who have severe kidney problems.

#### **Use in children and adolescents**

##### **Children and infants (6 months to 11 years)**

Your doctor will give Ranitidine by a slow injection into a vein at an initial dose of 2 or 2.5mg/kg over 10 minutes. The maximum dose is 50 mg every 6 or 8 hours. Sometimes treatment may be given by continuous infusion with a loading dose of 0.45mg/kg followed by an infusion of 0.15mg/kg/hr. It is usually only given while your child is unable to take Ranitidine by mouth.

For the prevention of stress ulcers in a seriously sick child, the recommended dose is 1mg/kg (maximum of 50mg) every 6 to 8 hours or 125-250 micrograms/kg/hr by continuous infusion.

##### **Adolescents (12 years and over)**

Same dosage as adults.

#### **Kidney Impairment**

If your kidneys are not working properly your doctor may give you a lower dose. Your dose may be halved to 25mg every 6 to 8 hours if you suffer from severe kidney problems.

If you have the impression that the effect of Ranitidine Injection is too strong or too weak, talk to your doctor. If you receive too much it is unlikely to cause any problems.

#### **If you take more Ranitidine Injection than you should**

Your doctor or nurse will give you Ranitidine 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 side effects below may sometimes happen.

**If you have an allergic reaction to this medicine see a doctor immediately.**

An allergic reaction may include:

- any kind of skin rash or "hives", flaking skin, severe itching of the skin, boils or sore lips, swelling (of the face, eyelids, lips, mouth or tongue), fever
- sudden wheezing, fluttering or tightness of the chest, chest pain, feeling faint especially when standing up or collapse.

**If you get any of the following side effects, speak to your doctor or nurse as soon as possible.**

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

- stomach ache (abdominal pain), constipation, feeling sick (nausea).

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

- skin rash (occasionally severe (red spots/purple spots or rash)) or itching
- changes in liver function tests and kidney function tests (types of blood test).

**Very rare (may affect up to 1 in 10,000 people):**

- feeling sick, loss of appetite with or without jaundice (yellow colour of skin and white of eyes) as this may be due to hepatitis (inflammation / infection of the liver)
- unusual tiredness, shortness of breath, bruising more easily or other signs of infection- this could be a sign of blood problems.
- slow or irregular heart beats, stopped heart beat (heart problems)
- severe stomach pain rarely caused by an inflamed pancreas or a change in the type of stomach pain
- feeling confused
- hallucinations (seeing, feeling or hearing things that are not there)
- feeling low (depression)
- inflamed blood vessels which may cause reddening of areas of skin, localized pain and tenderness.
- blurred vision
- kidney problems (symptoms may include a change in the amount of urine passed and its colour, vomiting)
- fainting
- headache or dizziness (sometimes severe)
- pains in muscles or joints
- uncontrolled movements. This usually stops once you stop taking this medicine.
- hair loss
- if you are a man, breast tenderness, breast enlargement or sexual impotence. This sexual impotence usually gets better once you stop taking this medicine.
- diarrhoea
- Inflammation of the pancreas (which may cause severe stomach pain).

**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 Website: [www.mhra.gov.uk/yellowcard](http://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 RANITIDINE INJECTION**

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

- do not store above 25°C.
- keep the ampoules in the outer carton in order to protect from light. Incorrect storage may lead to discolouration of your medicine.
- do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- if it is out of date or you no longer want it, take it back to the pharmacy.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION****What Ranitidine Injection contains**

The active substance is ranitidine hydrochloride. Each 2ml sterile solution for injection contains 50mg ranitidine (as ranitidine hydrochloride).

The other ingredients are sodium chloride, monopotassium phosphate, anhydrous disodium phosphate, water for injection and nitrogen.

**What Ranitidine Injection looks like and contents of the pack**

Ranitidine Injection is a colourless to almost colourless clear liquid.

It comes in glass ampoules each containing 2ml of solution and is packed in boxes of 5 ampoules each.

**Marketing Authorisation Holder**

Mercury Pharmaceuticals Ltd, Capital House, , 85 King William Street, London EC4N 7BL, United Kingdom

**Manufacturer**

Delpharm Tours, Rue Paul Langevin, 37170, Chambray Lès Tours, France.

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