

## Patient Information Leaflet

**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 pharmacist.
- \* This medicine has been prescribed for you only. 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 pharmacist. This includes any possible side effects not listed in this leaflet.

### What is in this leaflet:

- 1 What Ranitidine Oral Solution is and what it is used for
- 2 What you need to know before you take Ranitidine Oral Solution
- 3 How to take Ranitidine oral solution
- 4 Possible side effects
- 5 How to store Ranitidine oral solution
- 6 Contents of the pack and other information

## 1 What Ranitidine oral solution is and what it is used for

Ranitidine belongs to a group of medicines called H<sub>2</sub> antagonists, which reduce the amount of acid in your stomach.

For adults, this medicine is used to:

- \* heal and stop 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. This can cause pain or discomfort known as indigestion or heartburn
- \* stop ulcers from bleeding
- \* stop ulcers which may be caused by medicines called Non-Steroidal Anti-Inflammatories (NSAIDs), often used to treat arthritis
- \* stop acid coming up from the stomach while under anaesthetic during an operation.

For children (3 to 18 years), this medicine 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. This can cause pain or discomfort known as indigestion or heartburn.

## 2 What you need to know before you take Ranitidine Oral Solution

### Do not take Ranitidine if:

- \* you are allergic to Ranitidine or any of the other ingredients of this medicine (listed in Section 6). An allergic reaction can include a rash, itching or shortness of breath. If you are not sure, talk to your doctor or pharmacist before taking Ranitidine.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Ranitidine if:

- \* you have kidney problems
- \* you have a rare illness called porphyria
- \* you have lost weight recently and also have stomach ache, stomach pain or indigestion at the same time
- \* you are over 40 and recently had stomach ache, stomach pain or indigestion for the first time or which has recently changed
- \* you are over 65
- \* you have long term breathing problems
- \* you have diabetes
- \* you have any problems with your immune system.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Ranitidine.

You should see your doctor regularly if you are taking Ranitidine as well as a medicine for arthritis. This is particularly important if you are elderly or have ever had stomach problems.

### Other medicines and Ranitidine

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained 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 for pain and swelling (including arthritis) called Non-Steroidal Anti-Inflammatories (NSAIDs) such as indometacin or aspirin
- \* medicines for diabetes such as glipizide or glibenclamide
- \* medicines for heart problems called procainamide, N-acetylprocainamide or propranolol
- \* medicines to make you sleepy called triazolam or midazolam
- \* medicines for infections called raltegravir, atazanavir, delavirdine, ketoconazole, itraconazole or cefpodoxime
- \* medicines for cancer called gefitinib or lapatinib
- \* warfarin - to stop blood clots from forming
- \* lidocaine - a local anaesthetic
- \* diazepam - for worry or anxiety problems
- \* phenytoin - for epilepsy
- \* theophylline - for long term breathing problems
- \* sucralfate - for stomach ulcers.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Ranitidine.

### Pregnancy and breast-feeding

Do not take this medicine if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Ranitidine should not be taken during pregnancy or while breast-feeding unless considered essential by your doctor.

### Driving and using machines

The amount of alcohol in this medicine (8% w/v) may affect your ability to drive, cycle, or use any tools or machines.

### Important information about some of the ingredients of this medicine

Ranitidine Oral Solution contains:

- \* Ethanol (alcohol) - each 5ml spoonful contains 8% w/v ethanol, which is equal to 11ml of beer or 5ml of wine. Speak to the doctor before taking this medicine if you have an addiction to alcohol, liver disease, epilepsy, brain injury or disease, you are pregnant or if this medicine has been prescribed for a child.
- \* Sorbitol - a source of fructose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- \* 11mg of sodium per 5ml spoonful. You need to take this into account if you are on a controlled sodium diet.

## 3 How to take Ranitidine oral solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- \* Ranitidine Oral Solution contains 75mg of ranitidine (as hydrochloride) in each 5ml spoonful.
- \* Take this medicine by mouth only.

### Adults and children aged 12 years and above

The exact dose will depend on your particular stomach problem. Tell your doctor if you have taken all the medicine but still feel unwell. Also, if you are still taking your medicine but feel worse.

### To heal stomach or duodenal ulcers:

- \* the usual dose is either 150mg (two 5ml spoonful) in the morning and 150mg (two 5ml spoonful) in the evening for 4 weeks, **or**
- \* 300mg (four 5ml spoonful) at bedtime for 4 weeks
- \* your doctor may decide to continue your treatment in order to prevent the pain and discomfort returning.

### Rare diseases in which the acid production is very high:

The usual dose can be 600mg to 900mg (eight to twelve 5ml spoonful) each day or even higher.

### Children (3 to 11 years)

Your doctor will work out the right dose in mls based on your child's weight. Make sure you follow the instructions on the label.

### To heal stomach and duodenal ulcers:

The usual dose is 2mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 4mg for each kg, twice a day. Take each dose about 12 hours apart. The length of treatment may be increased to 8 weeks.

### To heal heartburn due to too much acid:

The usual dose is 2.5mg for each kg of body weight, twice a day for two weeks. This dose may be increased to 5mg for each kg, twice a day. Take each dose about 12 hours apart.

# Ranitidine® 150mg/10ml Oral Solution

Ref: xxx/xxx/020914/1/B

Please note that this medicine contains alcohol. See Section 2, Important information about some of the ingredients of this medicine, for more details.

## If you take more Ranitidine than you should

Taking more than it says on the label is unlikely to be dangerous, unless a lot of medicine is taken at once. In that case, talk to your doctor or go to your nearest accident and emergency department straight away.

## If you forget to take this medicine

- \* If you forget a dose, take it as soon as you remember it. Then go on as before.
- \* Do not take a double dose to make up for a forgotten dose.

## If you stop taking Ranitidine

After a few days of taking this medicine you should start to feel much better. Do not stop taking this medicine without talking to your doctor or pharmacist first, otherwise the pain and discomfort may come back.

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

## 4 Possible side effects

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

### Stop taking Ranitidine 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:
    - any kind of skin rash or "hives", flaking 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.
  - \* a change in the amount of urine passed and its colour, feeling sick (nausea) or being sick (vomiting), feeling confused, having a fever and rash – this could be a sign of kidney problems
  - \* severe stomach pain (possible sign of pancreatitis) or a change in the type of stomach pain
  - \* slow or irregular heartbeats
  - \* feeling unusually tired, short of breath, bruising more easily or getting more infections – this could be a sign of blood problems
  - \* red or purple spots or skin rash, which can be severe.
- Stop taking Ranitidine and see a doctor straight away if you notice any of the serious side effects above.

### Other side effects

**Tell your doctor if you notice any of following:**

### Uncommon (affects less than 1 in 100 people)

- \* stomach pain
- \* diarrhoea or constipation
- \* feeling sick (nausea)

### Rare (affects less than 1 in 1000 people)

- \* skin rash

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

- \* increase in creatinine level (kidney function)
- \* changes to liver function

### Very rare (affects less than 1 in 10,000 people)

- \* headache (sometimes severe)
- \* feeling dizzy or having blurred vision
- \* painful or swollen joints or muscles or movement in them that you cannot control
- \* rash, swollen joints and kidney problems – this could be a sign of swollen blood vessels (vasculitis)
- \* feeling depressed, confused or seeing, feeling or hearing things that are not there (hallucinations)
- \* hair loss
- \* breast tenderness or growth (in men)
- \* breast discharge (in men and women)
- \* feeling sick, loss of appetite with possible yellow skin or eyes (jaundice) – this could be a sign of a swollen liver (hepatitis)
- \* problems getting or keeping an erection (impotence). This usually gets better once you stop taking this medicine

### Not known (the frequency cannot be estimated from the available data)

- \* porphyria, a problem with your metabolism that can cause skin blisters, pain in and around your stomach (abdomen) and brain or nervous system problems.

Tell your doctor that you are taking Ranitidine if you have blood, urine or other tests carried out. This is because Ranitidine may affect the test results.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Ranitidine oral solution

Keep out of the sight and reach of children.

Do not store above 25°C

Do not use 1 month from the date you first open it.

Do not use Ranitidine oral solution after the expiry date which is stated on the carton and blister after (EXP). 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.

Do not use Ranitidine Oral Solution if you notice anything wrong with the medicine. Talk to your pharmacist.

Medicines should not be disposed of via waste water or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6 Contents of the pack and other information.

### What Ranitidine 150mg/10ml Oral Solution contains

The active substance is Ranitidine Hydrochloride. This medicine contains 150mg of Ranitidine (as Hydrochloride) in each 10ml of solution.

The other ingredients are disodium hydrogen phosphate anhydrous (E339), sodium dihydrogen phosphate dihydrate, saccharin sodium (E954), sorbitol solution 70% (E420), ethanol, garden mint flavour and purified water.

### What Ranitidine 150mg/10ml Oral Solution looks like and contents of the pack

Ranitidine 150mg/10ml Oral Solution is a white to pale yellow liquid which smells of mint. It comes in a brown glass bottle holding 300ml of solution.

### The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

### Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

### The manufacturer is:

Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE.

Revision date: 02/09/14

**POM**

Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.