

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. See section 4.

The name of your medicine is Ranitidine 150mg/10ml Oral Solution but it will be referred to as 'Ranitidine' throughout this leaflet.

What is in this leaflet:

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

1. What Ranitidine is and what it is used for

Ranitidine belongs to a group of medicines called H₂-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) Ranitidine is used to:

- ▶ heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- ▶ help clear up infection in your stomach, when taken with antibiotic medicines (medicines taken to treat germs)
- ▶ stop stomach ulcers when they are a side effect of some medicines
- ▶ 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 (3 to 18 years) Ranitidine 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 take Ranitidine

Do not take Ranitidine 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 taking Ranitidine.

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine if:

- ▶ you have stomach cancer
- ▶ you have kidney problems. You will need to take a different amount of Ranitidine
- ▶ you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- ▶ 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 any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and Ranitidine

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 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:

- ▶ Non-Steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation
- ▶ 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

- ▶ sucralfate for treating stomach ulcers.
- Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking Ranitidine before your operation in case he or she wants to give you midazolam.

If you are not sure talk to your doctor, pharmacist or nurse before taking Ranitidine.

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Ranitidine is not known to affect the ability to drive and use machines.

Ranitidine contains:

Ethyl parahydroxybenzoate (E214) and butyl parahydroxybenzoate: May cause allergic reactions (possibly delayed).

Sorbitol (E420): This medicine contains 700mg sorbitol in each 10ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicinal product contains 15.69mg sodium (main component of cooking/table salt) per dose of 10ml oral solution. This is equivalent to 0.8% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Ranitidine

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

The usual dose for an adult (including the elderly) is either:

- ▶ 10ml in the morning and 10ml in the evening, or
- ▶ 20ml at bedtime.

Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Use in children 12 years and over:

The adult dose is given.

Use in children from 3 to 11 years:

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

Treatment of stomach and duodenal ulcers:

The usual dose is 0.13ml (2mg) for each kg of body weight, twice a day for four weeks. This dose may be increased to 0.26ml (4mg) for each kg, twice a day. Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

Treatment of heartburn due to too much acid:

The usual dose is 0.16ml (2.5mg) for each kg of body weight, twice a day for two weeks. This dose may be increased to 0.33ml (5mg) for each kg, twice a day. Take each dose about 12 hours apart.

Route and Method of administration:

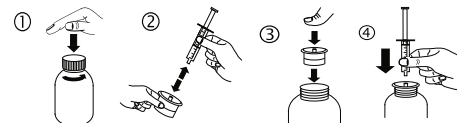
This medicinal product must be taken orally.

Use the measuring syringe provided in the pack to deliver the required dose.

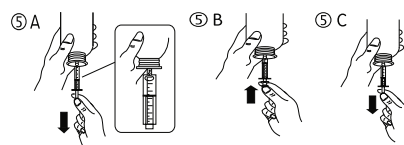
Do not mix Ranitidine with anything (not even water) before swallowing it.

Instructions for the use of syringe:

- a) Open the bottle: press the cap and turn it anticlockwise (figure 1).
- b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



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- d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Ranitidine than you should

Ranitidine is not normally harmful if you take more than you should, unless you take a lot of Ranitidine at once. If this applies to you (or someone else taking this medicine), **you should go to your nearest hospital casualty department straight away.** Take the medicine pack or any remaining medicine with you so that the doctor knows what you have taken.

If you forget to take Ranitidine

- ▶ If you forget a dose, take it as soon as you remember it, unless it is nearly time for your next dose.
- ▶ Do not take a double dose to make up for a forgotten dose.

If you stop taking Ranitidine

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

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

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 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:
 - 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 signs 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ranitidine

- ▶ Keep this medicine out of the sight and reach of children.
- ▶ Do not use this medicine after the expiry date which is clearly marked on the carton and bottle label after 'Exp'. The expiry date refers to the last day of the month.
- ▶ Do not store above 25°C.
- ▶ Discard 90 days after first opening.
- ▶ Keep the container in the outer carton in order to protect from light.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ 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 Ranitidine contains:

The active substance is ranitidine (as ranitidine hydrochloride).

Each 10ml of oral solution contains 150mg ranitidine as ranitidine hydrochloride.

The other ingredients are liquid, sorbitol (non-crystallising) (E420), saccharin sodium (E954), potassium dihydrogen phosphate (E340), disodium phosphate, anhydrous (E339), ethyl parahydroxybenzoate (E214), butyl parahydroxybenzoate, hypromellose (E464), garden mint flavor [contains propylene glycol (E1520)] and purified water.

What Ranitidine looks like and contents of the pack

Ranitidine oral solution is a clear pale yellow to yellow colour solution that smells of mint and supplied in amber glass bottles with child resistant plastic cap, a 10ml syringe with 0.25ml graduation for measuring the required dose and a bottle adaptor for syringe.

Ranitidine is supplied in bottles containing 100ml and 300ml oral solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Thame Laboratories,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 ONU, UK

POM

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

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