

Ranitidine 150mg/10ml Oral Solution (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.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Ranitidine 150mg/10ml Oral Solution (simply called Ranitidine Oral Solution throughout the rest of 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 Oral Solution contains a medicine called ranitidine. This belongs to a group of medicines called acid antagonists or H2-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) Ranitidine Oral Solution 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 Oral Solution 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 Oral Solution

Do not take Ranitidine Oral Solution:

- if you are allergic to ranitidine hydrochloride 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 Oral Solution.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ranitidine Oral Solution:

- if you have stomach cancer
- if you have kidney problems. You will need to take a different amount of Ranitidine Oral Solution
- if you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- if you have a rare condition called acute porphyria
- if you are over 65 years old
- if you have lung disease

- if you are diabetic
 - if you have any problems with your immune system.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and Ranitidine Oral Solution

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 Oral Solution can affect the way some other medicines work. Also some other medicines can affect the way Ranitidine Oral Solution 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 Oral Solution before your operation in case he or she wants to give you midazolam.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before taking Ranitidine Oral Solution.

Pregnancy, breast-feeding and fertility

If you are pregnant or 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

The amount of alcohol in a large dose of Ranitidine Oral Solution may affect your ability to drive or use machines.

Ranitidine Oral Solution contains ethanol (alcohol), sodium and sorbitol

Ranitidine Oral Solution contains ethanol (alcohol), i.e. up to 800 mg per dose. For this reason, it may be harmful for those suffering from alcoholism. The ethanol content should also be taken into account if medicine is to be given to pregnant or breast-feeding women, children and high risk groups such as those suffering from:

- alcoholism
- liver disease
- epilepsy
- brain injury or disease.

Each 5 ml spoonful contains approximately 400mg of alcohol which is equivalent to about two spoonfuls (10 ml) of beer or one spoonful (5 ml) of wine. Talk to your doctor or pharmacist if you are concerned. He/she may be able to suggest an alternative formulation.

Ranitidine Oral Solution contains sodium. If you have one or two 5ml spoonfuls, each dose will contain less than 23mg (less than 1 mmol) of sodium, i.e. it is essentially sodium free. If you have four 5ml spoonfuls, this will contain 39mg (1.68 mmol) of sodium. Tell your doctor if you are on a controlled sodium diet.

Ranitidine Oral Solution contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.



3. How to take Ranitidine Oral Solution

Taking this medicine

- take this medicine by mouth
- use the spoon provided to carefully measure the dose needed
- do not mix Ranitidine Oral Solution with anything (not even water) before swallowing it.

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

- two 5 ml spoonfuls in the morning and two 5 ml

Version No.:	XXXXXX/LF/035/02
Product Name:	Ranitidine 150mg/10ml Oral Solution
Pack Size:	300 ml
Component:	Leaflet
SKU:	XXXXXX
Market:	Ireland
Production Site:	Dales
Revision No.:	4
Revision Date:	06/10/2016
Revised by:	ADD
CRF:	AMCo.CRF.147.2016

Dimension:	148 x 260 mm
Commodity No.:	N/A
Pharma Code:	N/A
Core Spec Ref:	N/A
DCMF:	N/A
Print Colours:	302 C

Non-Print Colours: Cutter

Tech App. Date: 26/10/2015
Min. Font Size: 7 pt

REGULATORY AUTHORITY APPROVAL CONFIRMATION

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Accept Artwork / Reject Artwork (Please strike off whichever NOT applicable)

Signature

Name

Date

FOCUS

Version No.: XXXXXX/LF/035/02
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Pack Size: 300 ml
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Date

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- spoonfuls in the evening, or
- four 5 ml spoonfuls 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 mls 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 2 mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 4 mg 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 2.5 mg for each kg of body weight, twice a day for two weeks. This dose may be increased to 5 mg for each kg, twice a day. Take each dose about 12 hours apart.

If you take more Ranitidine Oral Solution than you should

Ranitidine Oral Solution is not normally harmful if you take more than you should, unless you take a lot of medicine 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 Oral Solution

- 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 Oral Solution

After a few days of taking the medicine you should start to feel much better. Do not stop taking the medicine 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 medicine, 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 Oral Solution 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; 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 Oral Solution

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and carton after Exp. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original carton/bottle in order to protect from light.

Once the bottle has been opened you should only use it for three months.

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 protect the environment.



6. Contents of the pack and other information

What Ranitidine Oral Solution contains

- The active substance is ranitidine hydrochloride. Each 10ml of Ranitidine Oral Solution contains 150mg of ranitidine (as hydrochloride).
- The other ingredients are sorbitol liquid (non crystallising), ethanol 96%, disodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate dihydrate, hydroxyethyl cellulose, peppermint flavour, saccharin sodium and water.

What Ranitidine Oral Solution looks like and contents of the pack

Ranitidine Oral Solution is a clear, pale yellow liquid with a smell of peppermint. It is available in an amber glass bottle containing 300ml of medicine.

Marketing Authorisation Holder

Focus Pharmaceuticals Limited
Capital House, 1st Floor, 85 King William Street,
London EC4N 7BL, UK.

Manufacturer

Dales Pharmaceuticals Ltd.,
Skipton, N Yorkshire, BD23 2RW, UK

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