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

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 (£338), sodium dihydrogen phosphate dihydrate, saccharin sodium (£954), sorbitol solution 70% (£420), ethanol, garden mint flavour and purified water.

Ranitidine 150mg/10ml Oral Solution is a white to pale yellow liquid which smells of mint. It comes in a brown glass bottle holding either 100ml or 300ml of solution.

What Ranitidine 150mg/10ml Oral Solution is and what it is used for

Ranitidine belongs to a group of medicines called H₂ 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.
- 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.

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 (£338), sodium dihydrogen phosphate dihydrate, saccharin sodium (£954), sorbitol solution 70% (£420), ethanol, garden mint flavour and purified water.

How to store Ranitidine Oral Solution

- Keep this medicine 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 after the expiry date (month, year) 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- If it is out of date or you no longer want it, take it to the back of the store.
- Do not use Ranitidine Oral Solution if you notice anything wrong with the medicine. Take it to your pharmacist.
- Do not throw away 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.

Warnings and precautions

- Do not take Ranitidine if:
  - you have any problems with your immune system.
  - you have long term breathing problems
  - you have a rare illness called porphyria
  - you have kidney problems. You will need to take a different amount of Ranitidine
  - you have a rare illness called porphyria
  - you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
  - 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.

Continued overleaf
Other medicines and Ranitidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes over-the-counter 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-Inflammatory Drugs (NSAIDs) such as indomethacin or aspirin
- medicines for diabetes such as glipizide or glibenclamide
- medicines for heart problems called procainamide, N-acetyprocainamide or propranolol
- medicines to make you sleepy called trizolam or midazolam. Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking midazolam before your operation in case he or she wants to give you midazolam.
- medicines for infections called rifampicin, azithromycin, 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 diseases, 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 spoonfuls) in the morning and 150mg (two 5ml spoonfuls) in the evening for 4 weeks, or
- 300mg (four 5ml spoonfuls) at bedtime for 4 weeks
- you may need to continue your treatment in order to prevent the pain and discomfort returning.

Rare diseases in which the acid production is very high:

To heal heartburn due to too much acid:
- the usual dose is 2.5mg 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.
- the usual dose about 12 hours apart. The length of treatment may be increased to 8 weeks.

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 usual dose is 3mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 6mg for each kg, twice a day. Take each dose about 12 hours apart.

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.

To heal stomach and duodenal ulcers:
- the usual dose is 1mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 1.5mg for each kg, twice a day. Take each dose about 12 hours apart.
- the usual dose about 12 hours apart. The length of treatment may be increased to 8 weeks.

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
  - 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
  - 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 the following:

Uncommon (affects less than 1 in 100 people)
- stomach pain
- 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 blured vision
- painful or swollen joints or muscles or movement in them that you cannot control
- a 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)
- flushing or marks on your skin that look like targets.

Continued overleaf
To heal stomach and duodenal ulcers:
The usual dose is 2mg per 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.

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.

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’, itchy skin, blisters or sores, swelling (of the face, lips, eyes, lips, mouth or tongue), fever
  - sudden wheezing, flushing 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 heartbeat
  - feeling unusually tired, short of breath, brushing 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 the following:

Uncommon (affects less than 1 in 100 people)

- stomach pain
- 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
- 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)
- flushing or marks on your skin that look like targets

Continued overleaf
1. What Ranitidine Oral Solution is and what it is used for

Ranitidine belongs to a group of medicines called H₂ 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.
- stop ulcers from bleeding
- 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 and stop problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach.
- stop acid coming up from the stomach while under anaesthetic during an operation.

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 a stomach condition – because it contains important information for you.
- you have any problems with your immune system.
- you have a rare illness called porphyria, a problem with your metabolism that can cause skin blisters, pain in and around your stomach (abdomen) and brain or nervous system problems.
- you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines – because it contains important information for you.
- you have kidney problems. You will need to take a different amount of Ranitidine.
- you have a rare illness called porphyria
- you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- 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.