

Consumer Medicine Information

Arrow - Ranitidine

Ranitidine hydrochloride, 150 mg and 300 mg tablets

What is in this leaflet?

This leaflet answers some common questions about ARROW - RANITIDINE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - RANITIDINE against the benefits they expect IT will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What ARROW - RANITIDINE are used for

ARROW - RANITIDINE is used to:

- treat peptic ulcers (gastric and duodenal ulcers)
- treat reflux oesophagitis (reflux disease)
- treat rare conditions called Zollinger-Ellison syndrome and scleroderma oesophagitis
- prevent duodenal ulcers and reflux disease from coming back.

Peptic ulcers:

ARROW - RANITIDINE is used to heal peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum, which is the tube leading out of the stomach. These ulcers usually cause pain and discomfort (indigestion) which is felt between the navel and the breast bone. The pain may occur before or after meals, or in the middle of the night.

ARROW - RANITIDINE IS also used to help stop duodenal ulcers from coming back.

Reflux disease:

ARROW - RANITIDINE is used to treat reflux oesophagitis, also called reflux disease, and stop it from coming back. This condition is caused by the washing back, or reflux, of food and acid from the stomach into the food pipe, also called the oesophagus. This causes a painful burning sensation in the chest rising up to the throat (heartburn), and usually occurs after eating or at night.

Zollinger-Ellison syndrome:

ARROW - RANITIDINE is used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

Scleroderma Oesophagitis:

ARROW - RANITIDINE is used to treat a rare condition called Scleroderma Oesophagitis, where the oesophagus is abnormal and there is reflux.

ARROW - RANITIDINE belongs to a group of medicines called histamine H₂-antagonists. These medicines work by reducing the amount of acid made by the stomach. This helps reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

Your doctor may have prescribed ARROW - RANITIDINE for another reason. Ask your doctor if you have any questions about why ARROW - RANITIDINE has been prescribed for you.

ARROW - RANITIDINE is not recommended for use in children under the age of 8, as there have been no studies of its effects in this age group.

ARROW - RANITIDINE is available only with a doctor's prescription.

There is no evidence that ARROW - RANITIDINE is addictive.

Before you take ARROW - RANITIDINE

When you must not take it

Do not take ARROW - RANITIDINE if you are allergic to:

- **ranitidine hydrochloride**
- **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itchiness or hives, swelling of the face, lips or tongue (which may cause difficulty in swallowing), shortness of breath, wheezing or difficulty breathing.

Do not take ARROW - RANITIDINE if the expiry date (Exp.) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take ARROW - RANITIDINE if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking ARROW - RANITIDINE during pregnancy.

Tell your doctor if you are breastfeeding.

ARROW - RANITIDINE passes into breast milk. Your doctor will discuss the risks and benefits of taking ARROW - RANITIDINE while breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney problems
- liver problems
- acute porphyria.

Tell your doctor if you have had to stop taking this, or any other medicine, for your ulcer or reflux.

Tell your doctor if you smoke.

If you have not told your doctor about any of the above, tell them before you start taking ARROW - RANITIDINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by ARROW - RANITIDINE, or may affect how well it works. These include sucralfate, another medicine used to treat peptic ulcer.

Your doctor can tell you what to do if you are taking this medicine.

If you are not sure whether you are taking this medicine, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicine to be careful with or avoid while taking ARROW - RANITIDINE.

How to take ARROW - RANITIDINE

How much to take

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition.

To heal peptic ulcers, the usual dose is 300 mg a day. This can be taken as 300 mg at bedtime or as 150 mg in the morning and 150 mg at night.

To help stop ulcers from coming back, the usual dose is one 150 mg tablet taken at night.

Follow all directions given to you by your doctor and pharmacist carefully.

If you forget to take ARROW - RANITIDINE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take two doses at a time to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take ARROW - RANITIDINE for

For peptic ulcers, ARROW - RANITIDINE needs to be taken for 4 to 8 weeks.

If you are taking ARROW - RANITIDINE to treat reflux disease, you may need to take it for up to 12 weeks.

Do not stop taking ARROW - RANITIDINE, even if you feel better unless advised by your doctor.

Stopping your tablets too early may let the ulcer come back.

Even when you have completed your tablets, your doctor may decide to continue your treatment with ARROW - RANITIDINE, possibly at a different dosage, in order to prevent the problem coming back again.

If you take too much ARROW - RANITIDINE (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (Australia- 13 11 26; New Zealand - 0800 POISON or 0800 764 766), or go to

Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ARROW - RANITIDINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ARROW - RANITIDINE

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking ARROW - RANITIDINE.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking ARROW - RANITIDINE.

If you become pregnant while taking ARROW - RANITIDINE, tell your doctor.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not use ARROW - RANITIDINE to treat any other conditions unless your doctor tells you to.

Do not give ARROW - RANITIDINE to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how ARROW - RANITIDINE affects you.

ARROW - RANITIDINE may cause dizziness or lightheadedness in some people. If either of these occur, do not drive, operate machinery, or do anything else that could be dangerous.

Suggestions that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures or for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Aspirin and many other medicines used to treat arthritis/period pain or headache - these medicines may irritate the stomach and make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.

- Caffeine - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because these contain ingredients that may irritate your stomach.
- Eating habits - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- Food - avoid foods that cause you pain or discomfort.
- Smoking - your doctor or pharmacist may advise you to stop smoking or at least cut down

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARROW - RANITIDINE.

Like all other medicines, ARROW - RANITIDINE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache
- tiredness, dizziness
- joint or muscle pains
- diarrhoea, constipation
- nausea (feeling sick), vomiting, stomach cramps or pain
- sleeping problems
- hair loss
- decreased sex drive, impotence
- abnormal uncontrolled movements, muscle twitching or spasms.

Tell your doctor immediately if you notice any of the following:

- yellowing of the skin or eyes
- depression, confusion, hallucinations
- fast, slow or irregular heartbeat
- severe upper stomach pain together with nausea or vomiting
- signs of frequent infections such as fevers, chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal
- general ill health associated with weight loss
- fever

- skin rash, redness, itching.

If any of the following happen, stop taking ARROW - RANITIDINE and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- hives or severe skin reactions
- swelling of the face, mouth, throat or limbs
- chest tightness, shortness of breath or difficulty breathing.

These may be signs of an allergic reaction to the tablets. Allergic reactions are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Some health problems may arise from your condition, rather than from the treatment. For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion which occurs during treatment
- vomiting
- passing black or blood-stained stools.

After using ARROW - RANITIDINE

Storage

Keep ARROW - RANITIDINE where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store ARROW - RANITIDINE or any other medicine in the bathroom or near a sink.

Do not leave ARROW - RANITIDINE in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - RANITIDINE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ARROW - RANITIDINE comes in 2 strengths of tablets:

- ARROW - RANITIDINE 150 - white, round tablet marked "150" on one side and ">" on the reverse.
Each blister pack contains 60 tablets and each bottle pack contains 250 tablets.
- ARROW - RANITIDINE 300 - white, oblong tablet marked "300" on one side and ">" on the reverse.
Each blister pack contains 30 tablets each bottle pack contains 250 tablets.

Ingredients

The active ingredient in ARROW - RANITIDINE is ranitidine (as hydrochloride).

- each ARROW - RANITIDINE 150 contains 150 mg of ranitidine
- each ARROW - RANITIDINE 300 contains 300 mg of ranitidine.

The tablets also contain:

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- Opadry II White YS-22-18096.

The tablets are gluten free.

Manufacturer

ARROW - RANITIDINE is supplied in Australia by:

Arrow Pharmaceuticals Limited

24 Rothschild Ave

Rosebery NSW 2018

ARROW - RANITIDINE is supplied in New Zealand by:

Arrow Pharmaceuticals NZ Limited

Unit B8 Mt Eden Central Business Park, 31-49 Normanby Rd, Mt Eden

Auckland, New Zealand.

Date of preparation

May 2003.