# **Ranitidine AN tablets**

Ranitidine hydrochloride tablets

#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about Ranitidine AN.

It does not contain all of 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 Ranitidine AN 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 Ranitidine AN is used for

The name of your medicine is Ranitidine AN. It contains the active ingredient ranitidine hydrochloride.

It belongs to a group of medicines called  $H_2$ -antagonists or  $H_2$ -blockers.

Ranitidine works by reducing the amount of acid produced by your stomach.

Ranitidine is used for the following:

- To treat and prevent peptic ulcers. Peptic ulcers are ulcers that occur in the stomach or duodenum.
- To treat reflux or heartburn
- Zollinger-Ellison Syndrome
- Scleroderma oesophagitis

By reducing the amount of acid produced by the stomach, Ranitidine AN reduces the pain associated with the above conditions, helps ulcers to heal and helps heal oesphagitis.

Your doctor may have prescribed Ranitidine AN for another reason. Ask your doctor if you have any questions about why Ranitidine AN has been prescribed for you.

Ranitidine AN is available only with a doctor's prescription.

Ranitidine AN is not addictive.

#### Before you take Ranitidine AN

#### When you must not take it

#### Do not take Ranitidine AN if you have an allergy to ranitidine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash or fainting.

Do not take Ranitidine AN if you have or have had acute porphyria.

Do not take Ranitidine AN after the expiry date printed on the pack.

Do not take Ranitidine AN if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

If you are not sure whether you should start taking Ranitidine AN, talk to your doctor.

#### Use in children

Your child's doctor will discuss the risks and benefits of your child using Ranitidine AN.

#### Before you start to take it

## Tell your doctor if you have any allergies to:

- any other medicines
- any other substances, such as foods, dyes or preservatives.

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

Ranitidine AN may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of using Ranitidine AN if you are pregnant.

#### Tell your doctor if you are breastfeeding or plan to breastfeed.

Ranitidine AN passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using Ranitidine AN if you are breastfeeding.

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

- kidney problems
- liver problems
- acute porphyria.

If you have not told your doctor about any of the above, tell them before you use Ranitidine AN.

#### 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 and Ranitidine AN may interfere with each other. These include:

• sucralfate, another medicine used to treat peptic ulcers.

This medicine may be affected by Ranitidine AN or may affect how well it works. You may need to use different amounts of your medicine or take different medicines. Your doctor will advise you.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking Ranitidine AN.

#### How to take Ranitidine AN

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

#### How much to take

Your doctor will tell you how many tablets you will need to take each day. This depends on your condition and whether you are taking any other medicines.

#### How to take it

## Swallow Ranitidine AN with a full glass of water.

#### When to take it

It does not matter if you take Ranitidine AN before or after food.

### Take each dose of your Ranitidine AN at the same time each day.

Taking each dose of Ranitidine at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

#### How long to take it

If you are taking Ranitidine AN to heal an ulcer you may need to take it for 4 to 8 weeks.

If you are taking Ranitidine AN to treat reflux disease you may need to take it up to 3 months.

It is important that you take the full course of Ranitidine AN prescribed by your doctor so that your condition is properly treated.

Even when you finish your tablets, your doctor may want you to continue taking Ranitidine AN, possibly a different dose, to help stop the problem coming back again.

Continue taking Ranitidine AN for as long as your doctor prescribes.

#### If you forget to take it

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 it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

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

If you have trouble remembering when to take your tablets, ask your pharmacist for some hints.

#### If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Ranitidine AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

## While you are taking Ranitidine AN

#### Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Ranitidine AN.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rantidine AN.

If you become pregnant while taking Ranitidine AN, tell your doctor immediately.

#### Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use RANITIDINE AN to treat any other complaints unless your doctor tells you to.

#### Things to be careful of

Be careful driving or operating machinery until you know how Ranitidine AN affects you. Ranitidine AN may cause dizziness, drowsiness or light-headedness in some people. Make sure you know how you react to Rantidine AN before you drive a car, operate machinery or do anything else that could be dangerous if you are affected.

#### Side Effects

#### Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ranitidine AN.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

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

- dizziness, light-headedness or drowsiness
- headache
- muscle or joint pain
- constipation or diarrhoea
- feeling sick (nausea) or vomiting
- sexual problems
- difficulty sleeping
- abdominal pain
- blurred vision.

These side effects are usually mild.

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

- yellowing of the skin or eyes (jaundice)
- depression, confusion or hallucinations
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

#### If any of the following happen, stop taking Ranitidine AN and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

• any skin reaction, for example rash, itching, hives, flaking or peeling of the skin

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath or difficulty breathing
- chest pain, changes in heart rate (fast, slow or irregular)
- severe upper stomach pain often with nausea and vomiting.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor immediately if you develop any of the following, which may be complications of your condition rather than the treatment:

- ongoing stomach pains
- unexpected weight loss
- passing black or bloody motions
- vomiting blood.

## After taking Ranitidine AN

#### Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the box or the blister pack they will not keep well.

Keep your Ranitidine AN in a cool dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink.

## Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

### Keep this medicine where children cannot reach it.

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

#### Disposal

If your doctor tells you to stop taking Ranitidine AN, 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

- RANITIDINE AN 150 mg tablets (AUST R 148523) are round, creamish-yellow, biconvex, film-coated tablets printed with RAN 150 in black ink on one side. Available in aluminium blister packs of 14, 20, 28, and 60 tablets.
- RANITIDINE AN 300 mg tablets (AUST R 148526) are round, creamish-yellow, biconvex, film-coated tablets printed with RAN 300 in black ink on one side. Available in aluminium blister packs of 7, 10, 14 and 30 tablets.

#### Ingredients

#### **Active Ingredient:**

Ranitidine hydrochloride

Each tablet may contain either 150 or 300 mg ranitidine (as hydrochloride) per tablet.

#### Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- castor oil
- magnesium stearate

- colloidal anhydrous silica
- purified talc
- titanium dioxide
- iron oxide yellow
- purified water
- OPACODE monogramming ink S-1-27794 BLACK.

Please read this leaflet carefully before you start taking Ranitidine AN. You may wish to keep it to read again.

## Name and Address of the Sponsor

**Amneal Pharma Australia Pty Ltd** 12 River St, South Yarra, VIC 3141 Australia

**Date of Preparation** September 2014

Ranitidine AN CMI v2.0