

## Ranital®

ranitidine hydrochloride tablets

### Consumer Medicine Information

#### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Ranital®.

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

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

#### WHAT RANITAL® IS USED FOR

This medicine is used to relieve the symptoms of gastro-oesophageal reflux such as heartburn and acid indigestion. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus.

Gastro-oesophageal reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn, as well as an unsettled stomach.

It contains the active ingredient ranitidine hydrochloride.

Ranitidine belongs to a group of medicines called H<sub>2</sub>- antagonists or H<sub>2</sub>-blockers.

It works by decreasing the amount of acid made by the stomach. This acid usually helps with the digestion of food, but an excess of this acid can result in gastro-oesophageal reflux.

Unlike antacid medications that work by neutralising the acidic content in the stomach, and only work for a few hours, Ranital® reduces the pain and relieves the symptoms of heartburn and indigestion by reducing acid production for up to twelve hours. This means that Ranital® works by preventing the excess acid problem, and also provides long lasting relief.

There is no evidence that Ranital® is addictive.

#### BEFORE YOU TAKE RANITAL®

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- ranitidine, the active ingredient, or any of the inactive ingredients mentioned at the end of this leaflet under Product Description
- any other similar medicines such as medicines for ulcer or reflux.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.**

*Before you start to take it*

**Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor or pharmacist if you have or have had any of the following medical conditions:**

- kidney or liver problems
- acute porphyria, an inherited blood condition
- are over 40 years of age, and it is the first time you have experienced symptoms of reflux or indigestion, or that these symptoms have recently changed
- peptic, duodenal, or stomach ulcer
- symptoms like vomiting, diarrhoea, passage of blood, "coffee ground" like substance in vomit or faeces, or unintended weight loss
- lung disease
- diabetes
- any condition where your immune system may be affected
- other medical conditions.

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

It may affect your developing baby if you take it during pregnancy.

The active ingredient in Ranital® passes into breast milk and there is a possibility that your baby may be affected.

Your doctor can discuss with you the risks and benefits involved.

**There is not enough information to recommend the use of this medicine for children under the age of twelve years.**

Do not use this medicine without consulting your child's doctor first.

**If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking Ranital®.**

*Taking other medicines*

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

Some medicines and Ranital® may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots
- triazolam and midazolam, medicines used as sedatives
- ketoconazole, an anti-fungal
- atazanavir and delaviridine, medicines used to treat HIV
- glipizide, a medicine used for diabetes
- gefitinib, a medicine used in the treatment of cancer
- sucralfate, another medicine used to treat reflux and ulcers.

These medicines may be affected by Ranital®, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

#### HOW TO TAKE RANITAL®

**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, ask your doctor or pharmacist for help.**

*How much to take*

**Adults and children over the age of twelve years**

The usual dosage is one tablet, to be taken when symptoms appear. If symptoms return or persist for more than one hour, take another tablet.

Do not take more than two tablets in a 24 hour period.

**Children under of age of twelve years**

Ranital® is not recommended for children under twelve years of age except under doctor's advice.

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Ranital® may not work as well and your problem may not improve.

*How to take it*

Swallow the tablet whole with a full glass of liquid.

*When to take Ranital®*

Take your medicine with or without food.

*How long to take Ranital®*

Ranital® is for short-term use only. If symptoms persist or worsen, please see your doctor or pharmacist.

*If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 131 126) or New Zealand 0800 POISON or 0800 764766) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else has taken too much Ranital®. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

#### WHILE YOU ARE TAKING RANITAL®

*Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ranital®.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

*Things you must not do*

**Do not take Ranital® to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine 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 Ranital® affects you.

This medicine may cause dizziness or light-headedness in some people.

#### Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

#### Things that may help your condition

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

#### Alcohol -

your doctor or pharmacist may advise you to limit your alcohol intake.

**Aspirin and similar medicines used to treat arthritis, period pain or headaches -** these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist can suggest other medicines you can take.

#### Caffeine -

your doctor or pharmacist may suggest to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they 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.

#### Smoking -

your doctor or pharmacist may advise you to stop smoking or at least cut down.

#### Weight -

if you are overweight, your doctor or pharmacist may suggest losing some weight to help your condition.

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## SIDE EFFECTS

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

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

#### Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- constipation, nausea (feeling sick), vomiting, and diarrhoea
- abdominal pain or discomfort.

These are mild, more common side effects of this medicine, and are short-lived.

- headache, sometimes severe
- tiredness, insomnia (sleeplessness)
- dizziness or drowsiness
- muscle and joint pain
- abnormal uncontrolled movements, muscle twitching or spasms
- depression
- breast tenderness and/or breast enlargement.

These are rare side effects of the medicine.

#### Tell your doctor or pharmacist as soon as possible if you notice any of the following:

- yellowing of skin or eyes (jaundice)
- confusion, depression and hallucination
- blurred vision
- skin troubles such as rash (red spots), itching, skin lumps or hives
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal.

The above list includes serious side effects that may require urgent medical attention.

Serious side effects are rare.

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

- swelling of the limbs, eyelids, face, lips, mouth or throat which may cause difficulty in swallowing or breathing, itchy rash or hives. These are the symptoms of an allergic reaction
- severe upper stomach pain together with nausea and vomiting
- chest pain, unusual heart beat (fast, slow or irregular).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

#### Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people

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## AFTER TAKING RANITAL®

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### Storage

Keep your medicine in the original container.

If you need to take it out of its original container it may not keep well.

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

Protect from light.

Do not store Ranital® or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

#### Keep it 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.

### Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## PRODUCT DESCRIPTION

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### What it looks like

Ranital® 150mg: yellow, round, film-coated tablets, scored on one side.

Available in blisters of 14 or 28 tablets.

### Ingredients

Active ingredient:

- Ranital® 150mg - 150mg ranitidine as ranitidine hydrochloride.

Inactive ingredients:

- microcrystalline cellulose
- calcium hydrogen phosphate
- maize starch
- sodium starch glycollate

- magnesium stearate
- colloidal
- anhydrous silica
- lactose
- hypromellose
- titanium dioxide
- macrogol 4000
- iron oxide yellow CI77492.

This medicine does not contain gluten.

### Supplier

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road,  
Macquarie Park, NSW 2113  
Australia  
Tel: 1800 634 500

Novartis New Zealand Ltd  
PO Box 99102  
Newmarket  
Auckland 1149  
New Zealand  
Tel: 0800 354 335

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### Australian Register Number

Ranital® 150mg film-coated tablets: AUST R 75206