

# Rani 2

Ranitidine (as hydrochloride)

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## CONSUMER MEDICINE INFORMATION

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### What is in this leaflet

This leaflet answers some common questions about Rani 2.

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 Rani 2 against the benefits expected 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.

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### What Rani 2 is used for

Rani 2 is used in the treatment of the following conditions:

#### Ulcers

Rani 2 is used to treat 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. Ulcers can be caused in part by too much acid being made in the stomach.

Rani 2 may also be used to help stop ulcers from coming back once they have healed.

#### Reflux oesophagitis

Rani 2 is used to relieve the symptoms of reflux oesophagitis. This can be caused by "washing back" (reflux) of food and acid from the stomach into the oesophagus (food pipe). Reflux can cause a burning feeling in the chest rising up to the throat, also known as heartburn.

#### Other conditions

Rani 2 is used to treat a rare condition called Zollinger-Ellison syndrome. In this condition the stomach produces very large amounts of acid, much more than in ulcers and reflux disease.

Rani 2 may be used to treat scleroderma oesophagitis. This is a rare condition in which the oesophagus is abnormal and there is reflux.

**Ask your doctor if you have any questions about why Rani 2 has been prescribed for you.**

Your doctor may have prescribed Rani 2 for another reason.

Rani 2 is not recommended for use in children under the age of 8, as there is not enough information about its effects in this age group.

There is no evidence that Rani 2 is addictive.

#### How Rani 2 works

Rani 2 belongs to a group of medicines called H<sub>2</sub> antagonists or H<sub>2</sub> blockers. These medicines work by decreasing the amount of acid made by the stomach. This helps reduce pain and allows any damage to heal.

Rani 2 is available only with a doctor's prescription.

There is no evidence that Rani 2 is addictive.

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### Before you take Rani 2

#### **When you must not take it**

**Do not take Rani 2 if you are allergic to:**

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

Symptoms of an allergic reaction may be mild or severe. They may include some or all of the following: wheezing, swelling of the lips or mouth, or difficulty in breathing.

**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 Rani 2, talk to your doctor.**

#### **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.**

The safety of Rani 2 in pregnancy has not been established. Rani 2 is not recommended for use during

pregnancy. If there is a need to consider Rani 2 during your pregnancy, your doctor will discuss with you the risks and benefits of taking it.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Rani 2 passes into breast milk. Your doctor will discuss the risks and benefits of taking Rani 2 when breastfeeding.

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

- \* kidney problems
- \* liver problems
- \* acute porphyria
- \* chronic lung disease
- \* diabetes
- \* a weakened immune system or lowered resistance to infection, sometimes caused by certain diseases or treatments.

Your doctor may want to take special care if you have any of these conditions.

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

**If you have not told your doctor about any of the above, tell them before you start taking Rani 2.**

***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, such as:**

- \* warfarin, used to prevent blood clots
- \* triazolam and midazolam, used as sedatives
- \* ketoconazole, used to treat fungus
- \* atazanavir and delaviridine, used to treat HIV
- \* glipizide, used for diabetics,
- \* gefitinib, used in the treatment of cancer.

Some medicines may be affected by Rani 2, 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 medicines to be careful with or avoid while taking Rani 2.

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## How to take Rani 2

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***How much to take***

The dose varies from person to person.

To treat an ulcer or reflux disease, 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 bedtime.

To prevent an ulcer from coming back, the usual dose is 150 mg at bedtime.

Different doses may be used depending on your condition. Your doctor will decide the right dose for you.

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

***How to take it***

**Swallow each tablet whole with a glass of water.**

Rani 2 can be taken with or without food.

***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 the missed dose 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 you missed.**

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

***How long to take it for***

If you are taking Rani 2 to heal an ulcer, you will need to take it for 4 to 8 weeks.

If you are taking Rani 2 to treat reflux disease, you may need to take it for up to 12 weeks.

It is very important that you take the full course of Rani 2 prescribed by your doctor so that your condition is properly treated.

Even when you have completed your tablets, your doctor may decide to continue your treatment with Rani 2, possibly at a different dosage, in order to prevent the problem coming back again.

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

**Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Rani 2. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## While you are taking Rani 2

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***Things you must do***

**Take Rani 2 exactly as your doctor has prescribed.**

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Rani 2.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rani 2.**

**If you become pregnant while taking Rani 2, tell your doctor immediately.**

### ***Things you must not do***

**Do not use Rani 2 to treat any other conditions unless your doctor tells you to.**

**Do not give Rani 2 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 Rani 2 affects you.**

Rani 2 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.

**Be careful drinking alcohol while taking Rani 2.**

Combining alcohol with Rani 2 may make you more dizzy or lightheaded.

### ***Suggestions that may help your condition***

Some self-help actions suggested below may help your condition.

Talk to your doctor or pharmacist about these and ask for more information.

\* **Alcohol -**

your doctor may advise you to limit your alcohol intake.

\* **Aspirin and similar medicines used to treat, for example, arthritis, period pain or headache -**

these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist can suggest other medicines you may take.

\* **Caffeine -**

your doctor may advise you to limit the number of drinks you take which contain caffeine, such

as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate the stomach.

\* **Eating habits -**

consider eating smaller quantities at regular meal times. Do not skip meals. Eat slowly and chew your food carefully. Try not to rush at meal times.

\* **Smoking -**

your doctor is likely to advise you to stop smoking or at least cut down the number of cigarettes you smoke. Ask for advice on how they can help you do this.

\* **Weight -**

if you are overweight, your doctor may suggest that you lose 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 Rani 2.**

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.

**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
- \* constipation, diarrhoea
- \* nausea (feeling sick), vomiting, stomach cramps or pain
- \* sleeping problems
- \* hair loss

- \* decreased sex drive, impotence
- \* abnormal uncontrolled movements, muscle twitching or spasms
- \* breast tenderness and/or breast enlargement
- \* breast discharge.

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

- \* yellowing of the skin or eyes (jaundice)
- \* depression, confusion, hallucinations
- \* fast, slow or irregular heartbeat
- \* severe upper stomach pain together with nausea and vomiting
- \* signs of frequent infections such as fever, 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 Rani 2 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 Rani 2. 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 the condition being treated itself, rather than the treatment. For this reason, contact your doctor immediately if you notice any of the following:**

- \* pain or indigestion which occurs during treatment with Rani 2
- \* vomiting

- \* passing black or blood-stained motions.

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## After taking Rani 2

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### **Storage**

**Keep Rani 2 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 blister pack until it is time to take them.**

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

**Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.**

**Do not store Rani 2 or any other medicine in the bathroom or near a sink. Do not leave Rani 2 in the car or on window sills.**

Heat and dampness can destroy some medicines.

### **Disposal**

**If your doctor tells you to stop taking Rani 2, or your medicine has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.**

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## Product description

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### **What it looks like**

Rani 2 comes as two strengths of tablets:

- \* 150 mg tablet: round white tablet marked RN 150 and a Greek alpha symbol. Each blister pack contains 60 tablets
- \* 300 mg tablet: capsule-shaped white tablet marked RN 300 and a Greek alpha symbol. Each blister pack contains 30 tablets.

### **Ingredients**

The active ingredient in Rani 2 is ranitidine (as ranitidine hydrochloride).

Rani 2 tablets contain either 150 mg or 300 mg of ranitidine. The tablets also contain:

- \* microcrystalline cellulose
- \* magnesium stearate
- \* Opadry White OY-S-7322 (includes colour 171).

The 300 mg tablets also contain:

- \* croscarmellose sodium.

Rani 2 is gluten and lactose free.

### **Supplier**

Rani 2 is supplied by:

**Alphapharm Pty Limited**

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

[www.alphapharm.com.au](http://www.alphapharm.com.au)

Medical Information

Phone: 1800 028 365

Australian registration numbers:

150 mg tablets - AUST R 59090

300 mg tablets - AUST R 59091

This leaflet was prepared on

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