

Rani 2

contains the active ingredient ranitidine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Rani 2.

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 Rani 2 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 Rani 2 is used for

Rani 2 is used to:

- treat stomach and duodenal ulcers (duodenal ulcers occur in the tube leading out of the stomach).
- prevent stomach and duodenal ulcers from coming back.
- treat and prevent reflux oesophagitis (also known as reflux), which is the washing back of food and acid from the stomach up into the food pipe. Reflux can cause heartburn, a painful burning sensation which occurs in the chest and rises up to the throat.
- treat Zollinger-Ellison syndrome, a rare disorder where the stomach produces very large amounts of

acid, much more than in ulcers and reflux disease.

- treat scleroderma oesophagitis, a rare condition in which the food pipe becomes thick and hardened, allowing acid to reflux.

Rani 2 belongs to a group of medicines called histamine₂ (H₂) antagonists or histamine₂ (H₂) blockers. These medicines work by reducing the amount of acid produced by the stomach. This helps to heal the ulcer and/or reflux disease.

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 have been limited studies of its effects in children of this age group.

There is no evidence that Rani 2 is addictive.

Before you take Rani 2

When you must not take it

Do not take Rani 2 if you are allergic to medicines containing ranitidine or any of the ingredients listed at the end of this leaflet.

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

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.

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 smoke.

Smoking may worsen your condition. Your doctor may advise you to reduce or stop smoking.

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

- kidney problems
- acute porphyria (rare disease of blood pigments)
- 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.

If you have not told your doctor or pharmacist about any of the above, tell him/her 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.

Some medicines and Rani 2 may interfere with each other. These include:

- sucralfate, another medicine used to treat stomach and/or duodenal ulcers
- warfarin, a medicine used to prevent blood clots
- triazolam, midazolam, used as sedatives
- ketoconazole, a medicine used to treat fungal infections
- atazanavir and delaviridine, medicines used to treat HIV infection
- glipizide, a medicine used to treat diabetes
- gefitinib, a medicine used to treat cancer.

You may need different amounts of your medicine, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

How to take Rani 2

How much to take

The dose varies from person to person.

The usual dose is 150 mg to 300 mg per day, taken as one 150mg tablet once or twice a day, or one 300mg tablet at night. Your doctor may advise you to take a different dose. This depends on your condition.

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

How to take it

Swallow the tablets with a glass of water.

When to take it

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

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 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 Rani 2. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Rani 2

Things you must do

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

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

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

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Rani 2.

Things you must not do

Do not stop taking Rani 2, or lower the dose, without checking with your doctor.

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 generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Rani 2

may cause dizziness or light-headedness in some people.

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 may advise you to limit your alcohol intake.
- Aspirin and many other medicines used to treat arthritis, period pain and headaches - these medicines may irritate the stomach and may 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 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 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 Rani 2.

Like all other medicines, Rani 2 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.

If you are over 65 years of age, you may have an increased chance of getting 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 or weakness
- sleeping problems
- dizziness
- decreased sex drive, impotence
- constipation, diarrhoea
- nausea, vomiting
- stomach cramps or pain
- muscle or joint pain
- hair loss
- blurred vision
- abnormal uncontrolled movements, muscle twitching or spasms.

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

- skin rash, redness, itching
- fast, slow or irregular heartbeat
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- yellow colouring of the skin or eyes
- general illness associated with weight loss
- depression, confusion, hallucinations.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- severe stomach pain or discomfort
- severe skin reactions
- swelling of the eyelids, face, throat or tongue causing difficulty breathing or swallowing
- severe chest pain or tightness.

Tell your doctor if you notice anything that is making you feel unwell.

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

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
- passing black or blood stained motions.

After taking Rani 2

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 pack until it is time to take them.

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

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

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 windowsills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

Rani 2 comes in 2 strengths of tablets:

- Rani 2 150 mg - creamish yellow, biconvex, round, film-coated tablets marked "G" on one side and "00" over "30" on the other. Each blister pack contains 60 tablets.
- Rani 2 300 mg- creamish yellow, biconvex, capsule-shaped, film-coated tablets marked "G" on one side and "0031" on the reverse. Each blister pack contains 30 tablets.

Ingredients

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

Each tablet contains 150 mg or 300 mg of ranitidine.

Rani 2 tablets contain the following inactive ingredients:

- microcrystalline cellulose
- magnesium stearate
- hypromellose
- castor oil
- ferric oxide yellow
- titanium dioxide
- purified talc

The 300 mg tablets also contain croscarmellose sodium.

The tablets are gluten free.

Supplier

Rani 2 is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Rani 2 150mg - AUST R 285696

Rani 2 300mg - AUST R 285693

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