#### Ranitidine hydrochloride

#### **Consumer Medicine Information**

#### About your Zantac Tablets

## Read all of this leaflet carefully before you take your medicine.

This leaflet does not have the complete information available about your medicine. If you have any questions about your medicine, you should ask your doctor or pharmacist (also known as chemist).

All medicines have some risks. Sometimes new risks are found even when a medicine has been used for many years.

If there is anything you do not understand, ask your doctor or pharmacist. If you want more information, ask your doctor or pharmacist.

#### What is in my Zantac?

The medicine in your Zantac tablets is called ranitidine (as hydrochloride). This belongs to a group of medicines called H2-antagonists.

### What does my Zantac do?

Zantac is mostly used to:

- treat stomach and duodenal ulcer disease (also known as peptic ulcer),
- stop these ulcers from coming back,
- treat reflux oesophagitis (also known as reflux).

These problems are caused, in part, by too much acid in the stomach. This can lead to pain such as heartburn. Zantac works by reducing the amount of acid in the stomach. This reduces the pain and also allows the ulcer and reflux to heal.

Zantac is also used to treat:

- · Zollinger-Ellison disease,
- · scleroderma oesophagitis.

#### Before you take it

#### Do not take if:

You must not take Zantac if:

- you have ever had an allergic (hypersensitive) reaction to ranitidine or any of the ingredients listed towards the end of this leaflet.
- the expiry date (EXP) printed on the pack has passed
- the packaging is torn or shows signs of tampering

### Tell your doctor if:

You must tell your doctor if:

- you are allergic to foods, dyes, preservatives or any other medicines
- you have ever had an allergic (hypersensitive) reaction to ranitidine or any of the ingredients listed towards the end of this leaflet.
- you are allergic to any medicine,
- · you have stomach cancer,
- · you have kidney disease,
- you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines.
- you have a disease known as acute porphyria.
- · you are over 65 years of age.
- you have lung disease.

- · you are diabetic.
- you have any problems with your immune system.
- you have to stop taking this or any other medicine for your ulcer or reflux.

#### Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, have taken any recently, or if you start new ones. This includes herbal medicines and any other medicines you have bought without a prescription.

Zantac can affect the way some other medicines work. Also other medicines can affect the way Zantac works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- warfarin, used to prevent blood clots
- triazolam and midazolam, used as sedatives
- · ketoconazole, an anti-fungal
- atazanavir and delaviridine, used to treat HIV
- glipizide, used for diabetics.
- gefitinib, used in the treatment of cancer.
- Non-Steroidal Anti- Inflammatory (NSAID) medicines, for pain and inflammation
- procainamide or n-acetylprocainamide, used to treat heart problems
- · sucralfate used to treat ulcers

# What if I am pregnant or breast feeding?

Tell your doctor if you are pregnant, likely to get pregnant or are breast feeding. Your doctor will tell you if you should take this medicine

#### How do I take it

- The dosage depends on the disease that you are suffering from. Your doctor or pharmacist will usually tell you how many Zantac tablets to take and how often to take them. You will also find this information on the label of your medicine.
- The normal adult dosage is 150 to 300 milligrams per day, taken as one 150 mg tablet once or twice a day, or one 300 mg tablet at bedtime. Your doctor may prescribe a different dosage.
- Do not take extra tablets. Do not take the tablets more often than you have been told
- It does not matter whether you take the tablets before or after food.
- Zantac tablets should be swallowed whole with a glass of water.
- Your pain or other symptoms may take a few days to go away.
- Take all the tablets your doctor has prescribed for you, even if you feel better.
- Even when you have completed your tablets, your doctor may decide to continue your treatment with Zantac, possibly at a different dosage, in order to prevent the problem coming back again.

#### Use in Children:

Zantac has not been studied fully in children. However, Zantac has been used with good results in children aged 8 to 18 years in doses up to 150 mg twice daily.

#### What should I do if I miss my dose?

If you forget to take your Zantac, take another as soon as possible unless it is nearly time for your next dose. Do not take a double dose to make up for the missed one.

#### Side effects

Like other medicines, Zantac may cause some side-effects. Most of the side-effects will be minor and temporary, but some may be serious. Your doctor will be able to answer any questions you may have.

Tell your doctor straight away and do not take any more Zantac if you have:

- an allergic reactions, the signs may include:
  - skin reactions such as rash (red spots),
     itching, skin lumps or hives
  - swelling of the eyelids, face, lips, tongue or other parts of the body
  - shortness of breath, trouble breathing,
     wheezing, chest pain or tightness
  - unexplained fever and feeling faint, especially when standing up.
- severe stomach pain or a change in the type of pain,
- yellow colouring of the skin or eyes (jaundice), confusion,
- general illness associated with weight loss
- fever.
- irregular heart beat (including unusually fast or slow heart beats),
- · changes to heart beat

If you get any of the following side-effects after taking Zantac tell your doctor, but there is no immediate reason to stop taking the tablets unless you are concerned:

- headache,
- · joint or muscle pains,
- · dizziness,
- · depression,
- constipation
- feeling sick (nausea) or vomiting
- diarrhoea
- breast tenderness and/or breast enlargement
- breast discharge.
- changes in liver function tests

If you notice any symptoms that concern you or if the tablets cause any other side-effects, tell your doctor or pharmacist.

If you have taken all the tablets and still do not feel better tell your doctor as soon as

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

#### Overdose

In the event of an overdose you should immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Zantac, even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

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#### How do I store my Zantac?

- Keep your Zantac tablets away from heat (store below 25 degrees C). For example, you should not leave them in the car on hot days.
- Please keep your Zantac tablets in a place where children cannot reach them.
- You will find an "expiry" (or use by)
  date printed on the manufacturer's label
  of the pack. Do not use the tablets after
  this date. Do not use the tablets if they
  are discoloured.
- Keep your Zantac tablets away from moisture. Leave the tablets in the pack until you are ready to use them.

# Can I let someone else use my Zantac?

Never give this medicine to someone else. The medicine is only for you. It may harm other people even if they seem to have the same symptoms that you have.

### Product description

#### What Zantac tablets look like.

Zantac tablets come in two strengths:

- Zantac 150 mg tablets are white, filmcoated tablets engraved "150" on one face and plain on the other.
- Zantac 300 mg tablets are white capsuleshaped, film-coated tablets engraved "300" on one face and plain on the other.
- Pack sizes available: 150 mg 7's, 14's 28's and 60 tablets; 300 mg - 7's 14's and 30 tablets.
- \*Some pack sizes may not be available

#### Ingredients

Zantac contains the active ingredient ranitidine (as ranitidine hydrochloride). Each tablet contains either 150 or 300 milligrams of ranitidine.

Your tablets also contain the following inactive ingredients.

microcrystalline cellulose, magnesium stearate, croscarmellose sodium and Opadry II white YS-22-18096

Each Zantac 300 mg tablet contains 0.8 mg of sodium

Zantac tablets are free from gluten and lactose.

## Who makes my Zantac?

Zantac is made for:

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street St Leonards NSW 2065 Australia.

# Do not throw this leaflet away. You may need to read it again.

Zantac 150 mg tablets [AUST R 427731]: Zantac 300 mg tablets [AUST R 53323]:

Zantac 150 mg (OTC) [AUST R 445896]:

Zantac Double Strength 300 mg tablets [AUST R 95076]:

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