# Zantac® Syrup

Ranitidine (as hydrochloride) oral solution

### **Consumer Medicine Information**

## What is in this leaflet?

Please read this leaflet carefully before you start Zantac Syrup.

This leaflet answers some common questions about Zantac Syrup. 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 risks and benefits. Your doctor has weighed the risks of you taking Zantac Syrup against the benefits this medicine is expected to have for you.

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 Zantac Syrup is used for

Zantac Syrup belongs to a group of medicines called H2-antagonists.

Zantac Syrup 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 or heartburn).

Zantac Syrup is also used to treat:

- Zollinger-Ellison disease,
- Scleroderma oesophagitis.

These problems are improved by reducing the amount of acid in the stomach. Zantac Syrup reduces stomach acid to decrease pain and allow the ulcer and reflux to heal.

Your doctor may have prescribed Zantac Syrup for another reason.

Ask your doctor if you have any questions about why Zantac Syrup has been prescribed for you.

Zantac Syrup is not addictive.

# Before you take Zantac Syrup

# When you must not take Zantac Syrup

Do not take Zantac Syrup if you have ever had an allergic reaction to ranitidine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

#### Do not take Zantac Syrup if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using Zantac Syrup if you are pregnant or breastfeeding.

# Do not take Zantac Syrup after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take Zantac Syrup if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be taking Zantac Syrup, talk to your doctor.

# Before you start to take Zantac Syrup

You must tell your doctor:

- If you are allergic to foods, dyes, preservatives or any other medicines,
- If you have had to stop taking this or any other medicine for your ulcer or reflux,
- If you have kidney disease,
- If you have a disease known as acute porphyria.
- If you have stomach cancer
- If you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines.
- If you are over 65 years of age.
- If you have lung disease.
- If you are diabetic.
- If you have any problems with your immune system.

#### Taking other medicines

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

Zantac Syrup contains alcohol

Zantac Syrup contains 7.5% w/v alcohol. Each spoonful (5 mL) of syrup therefore contains up to 375 mg. It may be harmful if you are an alcoholic. You also need to be aware of the alcohol content:

- if you are pregnant or breastfeeding
- if you have epilepsy, liver disease, or have had an injury to your brain or other condition affecting your brain
- if your child is being treated.

It may also change or increase the affect of other medicines.

Talk to your doctor if you are concerned. They may suggest an alternative treatment.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Zantac Syrup with other medicines.

# How to take Zantac Syrup

The Pharmacist's label on the pack will tell you how to take Zantac Syrup. If there is something you do not understand, ask your doctor or pharmacist.

### How much to take

The dosage depends on the disease that you are suffering from.

The normal adult dosage is 10 to 20 mL by metric measure per day, taken as a 10 mL dose once or twice a day, or a 20 mL dose at bedtime. Your doctor may prescribe a different dosage.

If you are giving Zantac Syrup to a child, follow your doctor's instructions.

Do not take extra doses of the syrup. Do not take the syrup more often than you have been told.

### How to take Zantac Syrup

Your Zantac Syrup should be swallowed.

Do not mix Zantac Syrup with anything (not even water) before taking.

### When to take Zantac Syrup

Your doctor or pharmacist will be able to tell you when you should take your Zantac Syrup.

It does not matter whether you take the syrup before or after food.

### How long to take Zantac Syrup

Your pain or other symptoms may take a few days to go away.

It is important that you keep taking the medicine until you finish the full course of treatment prescribed.

Even when you have finished taking your Zantac Syrup, your doctor may decide to continue your treatment with Zantac, possibly at a different dosage, in order to prevent the problem coming back again.

# If you forget to take Zantac Syrup

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, then go back to taking it as you would normally.

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

# If you take too much (overdose)

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 Syrup, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

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

# While you are taking Zantac Syrup

### Things you must do

Tell your doctor or pharmacist that you are taking Zantac Syrup if you are taking or are about to be started on any new medicines including medicines you buy without a prescription such as:

- 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 nacetylprocainamide, used to treat heart problems
- sucralfate used to treat ulcers

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

#### Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

### Things you must not do

Do not stop taking Zantac Syrup, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours. Do not use Zantac Syrup to treat any other complaints unless your doctor says to.

### Things to be careful of

#### Be careful driving or operating machinery until you know how Zantac Syrup affects you.

Zantac Syrup generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Zantac Syrup may cause dizziness/drowsiness/tiredness in some people.

# Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Zantac Syrup, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Zantac Syrup can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported sideeffects are:

- Feeling sick (nausea),
- Vomiting,
- Stomach discomfort/pain,
- Constipation,
- Diarrhoea,
- Skin rash.

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

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

- Skin troubles such as rash (red spots), itching, skin lumps or hives,
- Swelling of the eyelids, face or lips,
- Wheezing, chest pain or tightness,

- Irregular heart beat (including unusually fast or slow heart beats),
- Changes to heart beat
- Severe stomach pain or a change in the type of pain,
- Yellow colouring of the skin or eyes (jaundice),
- Kidney problems (symptoms may include changes in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash),
- Confusion,
- Repeated infections,
- Blurred vision,
- Fever.

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

- headache
- joint or muscle pains
- dizziness
- depression
- breast tenderness and/or breast enlargement
- breast discharge.
- changes in liver function tests

If you think you are having an allergic reaction to Zantac Syrup, TELL YOUR DOCTOR IMMEDIATELY or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- Wheezing,
- Swelling of the lips/mouth,
- Difficulty in breathing,
- Hay fever,
- Lumpy rash ("hives"),
- Fainting.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Ask your doctor or pharmacist if you don't understand anything in this list.

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

# After taking Zantac Syrup

### Storage

# Keep this medicine where young children cannot reach it.

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

Store your Zantac Syrup away from heat (below 25°C).

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

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

Heat and dampness can destroy some medicines.

# Keep your Zantac Syrup in its bottle until it is time to take it.

If you take the syrup out of its bottle it may not keep well.

### Disposal

If your doctor tells you to stop taking Zantac Syrup, or the syrup has passed its expiry date, ask your pharmacist what to do with any syrup left over.

## Product description

## What Zantac Syrup looks like

Zantac Syrup is a clear, pale yellow, peppermint-flavoured liquid contained in a 300 mL amber glass bottle. Do not use the syrup if it is discoloured or lumpy. A double-ended measuring spoon (2.5mL/5mL) is provided for taking Zantac Syrup.

#### Ingredients

Zantac Syrup contains the active ingredient ranitidine (as hydrochloride).

Zantac Syrup also contains Hypromellose (464), alcohol (7.5% w/v), propyl and butyl hydroxybenzoate, potassium phosphate (515), sodium phosphate (514), sodium chloride, saccharin (954) sodium, sorbitol (420), mint flavour and water.

#### Manufacturer

Your Zantac Syrup is supplied by: Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street St Leonards NSW 2065 Australia

### Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

#### Do not throw this leaflet away.

You may need to read it again.

The information provided applies only to: Zantac®Syrup.

Zantac Syrup: AUST R 35188.

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