

Package Leaflet: Information for the User

Zantac 150 mg/ 10 ml Syrup ranitidine (as hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Zantac is and what it is used for
- 2 What you need to know before you take Zantac
- 3 How to take Zantac Syrup
- 4 Possible side effects
- 5 How to store Zantac
- 6 Contents of the pack and other information

1 What Zantac is and what it is used for

Zantac contains a medicine called ranitidine. This belongs to a group of medicines called H₂-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) Zantac is used to:

- treat ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- prevent stomach ulcers when they are a side effect of some medicines
- treat problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as 'indigestion', 'dyspepsia' or 'heartburn'
- treat other conditions where reduction of acid in the stomach is likely to be beneficial
- treat Zollinger-Ellison syndrome – a condition in which there is increased production of the hormone gastrin

For children (3 to 18 years) Zantac is used to:

- treat ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- treat problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as "indigestion", "dyspepsia" or "heartburn"

2 What you need to know before you take Zantac

Do not take Zantac if:

- you are allergic (hypersensitive) to ranitidine or any of the other ingredients of Zantac (listed in Section 6).

If you are not sure, talk to your doctor or pharmacist before taking Zantac.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zantac if:

- you have stomach cancer
- you have kidney problems. You will need to take a different amount of Zantac
- you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- you have a rare condition called acute porphyria
- you are a smoker
- you suffer from long-term lung disease, diabetes, are over 65 years or are unable to resist infection as you may be at increased risk of getting a serious chest infection (pneumonia); symptoms include fever, cough and breathlessness.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

You should see your doctor on a regular basis if you are taking Zantac long-term (maintenance therapy).

Children under 3 years of age

Zantac is not recommended in children under 3 years of age

Other medicines and Zantac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Zantac can affect the way some other medicines work. Also some other medicines can affect the way Zantac works.

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

- Non-Steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation
 - lidocaine, a local anaesthetic
 - propranolol, procainamide or n-acetylprocainamide, for heart problems
 - diazepam, for worry or anxiety problems
 - phenytoin, for epilepsy
 - theophylline, for breathing problems (asthma)
 - Certain Anticoagulants (e.g. Warfarin), for thinning your blood, as Zantac may alter the effect of these medicines
 - glipizide, for lowering blood glucose
 - atazanavir or delaviridine, for treating HIV infection
 - triazolam, for insomnia
 - gefitinib, for lung cancer
 - ketoconazole, an anti fungal medicine, sometimes used for treating thrush.
 - erlotinib; for certain types of cancer
-
- Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking Zantac before your operation in case he or she wants to give you Midazolam.
 - Sucralfate, for treating stomach ulcers.

If you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines (used to treat pain and inflammation) at the same time as Zantac you will need to see your doctor regularly.

If you are taking erlotinib, a drug used for the treatment of certain types of cancer, talk to your doctor before you take Zantac Syrup. Ranitidine contained in Zantac Syrup may decrease the amount of erlotinib in your blood and your doctor may need to adjust your treatment if it is used while you are receiving erlotinib.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Zantac.

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Zantac is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients of Zantac Syrup contains sodium, potassium, ethanol (alcohol), propyl hydroxybenzoate, butyl hydroxybenzoate and sorbitol.

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.

This medicine contains potassium, less than 1 mmol (39 mg) per 10 ml, i.e. essentially 'potassium-free'.

This medicine contains 700 mg sorbitol in each 10ml, which is equivalent to 70 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicinal product contains approximately 7.5% w/v ethanol (alcohol), i.e. up to 405 mg per 5 ml spoonful which is equivalent to about 11 ml of beer or 5 ml of wine. For this reason, it may be harmful for those suffering from alcoholism. The ethanol content should also be taken into account if Zantac Syrup is to be given to pregnant or breast-feeding women, children and high risk groups such as those suffering from:

- alcoholism
- liver disease
- epilepsy
- brain injury or disease

Talk to your doctor or pharmacist if you are concerned. An alternative formulation of ranitidine may be considered necessary for at-risk groups, including children; pregnant or breast-feeding women; those suffering from alcoholism, epilepsy, brain injury or disease.

This medicine also contains propyl hydroxybenzoate and butyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3 How to take Zantac Syrup

Always take Zantac exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Do not mix Zantac Syrup with anything (not even water) before swallowing it.

The usual dose for an adult (including the elderly) and adolescents (12 years and over) is either:

- two 5 ml spoonfuls in the morning and two 5 ml spoonfuls in the evening, **or**
- four 5 ml spoonfuls at bedtime.

In certain cases treatment may be given at a higher dose, up to four 5ml spoonfuls Twice Daily, and may last 8-12 weeks. Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Use in Children from 3 to 11 years:

Your doctor will work out the right dose in mls based on your child's weight. Make sure you follow the instructions on the label.

Treatment of stomach and duodenal ulcers:

The usual dose is 2 mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 4 mg for each kg, twice a day to a maximum dose of 300 mg per day (maximum dose of 20 ml per day). Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

Treatment of heartburn due to too much acid:

The usual dose is 2.5 mg for each kg of body weight, twice a day. This dose may be increased to 5 mg for each kg, twice a day to a maximum dose of 600 mg (40 ml) per day. Take each dose about 12 hours apart.

If you take more Zantac than you should

It is important to keep to the dose on the label of your medicine. Zantac is not normally harmful if you take more than you should, unless you take a lot of syrup at once. If this applies to you (or someone else taking this medicine), **you should go to your nearest hospital casualty department straight away**. Take the medicine pack or any remaining medicine with you so that the doctor knows what you have taken.

If you forget to take Zantac

- If you forget a dose, take it as soon as you remember it, unless it is nearly time for your next dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Zantac

After a few days of taking the syrup you should start to feel much better. Do not stop taking the syrup without talking to your doctor or pharmacist first, otherwise the original pain and discomfort may come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you need to look out for

Severe allergic reaction: These are rare in people taking Zantac. Signs include:

- raised and itchy rash (*hives*)
- swelling, sometimes of the face or mouth (*angioedema*)
- chest pain, shortness of breath, unexplained fever, wheezing or difficulty in breathing
- feeling faint, especially when standing up
- collapse

Contact a doctor immediately if you get any of these symptoms. Stop taking Zantac.

Serious skin reactions: these are very rare in people taking Zantac. Signs include:

- Skin rash, which may blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge).

Contact a doctor immediately if you get any of these symptoms. Stop taking Zantac.

Uncommon side effects

These may affect **up to 1 in 100** people

- Abdominal pain
- Constipation
- Nausea

Rare side effects

These may affect **up to 1 in 1,000** people:

- Allergic reactions
- Skin rash
- Elevation of Creatinine
- Changes to liver function

Very rare side effects

These may affect **up to 1 in 10,000** people:

- inflammation of blood vessels (*vasculitis*)
- inflammation of the pancreas (*pancreatitis*)
- inflammation of the liver (*hepatitis*), sometimes with yellowing of the whites of the eyes or skin (*jaundice*)
- inflammation in the kidney (*interstitial nephritis*)
- slow, fast or irregular heartbeat
- diarrhoea
- feeling confused, depressed, or seeing or hearing things that are not really there (*hallucinations*)
- joint or muscle pain, or uncontrolled movement
- headache, dizziness, blurred vision
- unusual hair loss or thinning (*alopecia*)
- unable to get or maintain an erection (*impotence*)
- unusual secretion of breast milk or breast enlargement in men.
- low levels of white blood cells
- decrease in number of blood platelets (cells that help blood to clot)
- decrease in number of all types of blood cells.

Not known (frequency cannot be estimated from the available data)

- shortness of breath

Speak to your doctor if you experience unexplained bruising, recurrent infection, tiredness or fainting.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax +353 1 6762517. Website www.hpra.ie; email: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Zantac

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle and the carton after Exp. The expiry date refers to the last day of the month.
- Do not store above 25°C
- Once opened, use within 28 days
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of pack and other information

What Zantac contains:

- The active substance is ranitidine (as hydrochloride). Each 10 ml of syrup contains ranitidine hydrochloride equivalent to 150 mg of ranitidine.
- The other ingredients are hypromellose, ethanol, propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate, potassium dihydrogen orthophosphate, disodium hydrogen orthophosphate anhydrous, sodium chloride, saccharin sodium, sorbitol 70% non-crystallising solution, mint flavour, purified water.
- Each 10 ml does contains 7.5% w/v ethanol (alcohol) i.e. up to 800 mg per dose.
- 10 ml of Zantac Syrup contains 15.54 mg of sodium.

What Zantac looks like and contents of the pack

Zantac Syrup is a clear, pale yellow liquid that smells of mint.

Cartons contain one 300 ml amber glass bottle.

A double ended 5 ml/2.5 ml spoon is included.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturer: Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany.

The information provided applies only to Zantac Syrup.

This leaflet was last revised in May 2019.

Reason for update: Updated in line with PSUSA and schedule check update.

Market: IE

Agency Approval Date:

Text Date: 23/05/2019

Text Issue and Draft No.: Issue 4 Draft 1

Trade marks are owned by or licensed to the GSK group of companies.

© 2019 GSK group of companies or its licensor