

Package Leaflet: Information for the User

Zantac[®] Syrup ranitidine 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, pharmacist or nurse.
- 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, pharmacist or nurse. 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:

- heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- help clear up infection in your stomach, when taken with antibiotic medicines (medicines taken to treat germs)
- stop stomach ulcers when they are a side effect of some medicines
- stop ulcers from bleeding
- improve 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'
- stop acid coming up from the stomach while under anaesthetic during an operation.

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

- heal ulcers in the stomach, of the part of the gut it empties into (the duodenum)
- heal and stop 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 to ranitidine or any of the other ingredients of this medicine (listed in Section 6).

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

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine 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 over 65 years old
- you have lung disease
- you are diabetic
- you have any problems with your immune system.

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

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)
- warfarin, for thinning your blood
- 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.

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.

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

Pregnancy and breast-feeding

If you are pregnant, might become pregnant or are breast-feeding, you should not take this medicine unless your doctor advises it is essential.

Ask your doctor, pharmacist or nurse for advice before taking any medicine, if you are pregnant or breast-feeding.

Zantac Syrup contains ethanol (alcohol), propyl hydroxybenzoate, butyl hydroxybenzoate and sorbitol

Zantac Syrup contains ethanol (alcohol), i.e. up to 800 mg per dose. 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.

Each 5 ml spoonful contains approximately 400mg of alcohol which is equivalent to about two spoonfuls (10 ml) of beer or one spoonful (5 ml) of wine. Talk to your doctor or pharmacist if you are concerned. He/she may be able to suggest an alternative formulation.

This medicine also contains propyl hydroxybenzoate and butyl hydroxybenzoate which may cause allergic reactions (possibly delayed) and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Zantac Syrup

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

Taking this medicine

- Take this medicine by mouth.
- Use the spoon provided to carefully measure the dose needed.
- Do not mix Zantac Syrup with anything (not even water) before swallowing it.

The usual dose for an adult (including the elderly) is either:

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

Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Children 12 years and over:

The adult dose is given.

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. 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 for two weeks. This dose may be increased to 5 mg for each kg, twice a day. Take each dose about 12 hours apart.

If you take more Zantac than you should

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.

The following side effects may happen with this medicine.

Stop taking Zantac and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reactions, the signs may include:
 - rash, itching or hives on the skin
 - swelling of your face, lips, tongue or other parts of the body
 - chest pain, shortness of breath, wheezing or having trouble breathing
 - unexplained fever and feeling faint, especially when standing up.
- kidney problems, which can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood tests
- severe stomach pain, this may be signs of something called ‘pancreatitis’
- a slow or irregular heartbeat.

Check with your doctor **at your next visit** if you notice any of the following:

Uncommon (may affect up to 1 in 100 people)

- stomach pain
- constipation
- feeling sick (nausea)

Rare (may affect up to 1 in 1,000 people)

- skin rash

Rare side effects that may show up in blood tests:

- increase of serum creatinine in the blood (kidney function test)
- changes to liver function

Check with your doctor **as soon as possible** if you notice any of the following:

Very rare (may affect up to 1 in 10,000 people)

- there can be changes in the level of certain substances in your blood. This can lead to you feeling unusually tired or short of breath and being more likely to bruise or get an infection
- feeling depressed, confused, seeing or hearing unexplained things (hallucinations)
- headache (sometimes severe)
- feeling dizzy or having blurred vision
- your joints or muscles are painful or swollen or you cannot control their movement
- your small blood vessels can become swollen (known as 'vasculitis'). Signs of this can include: a rash, swollen joints or kidney problems
- your liver can become swollen. This can lead to: nausea (feeling sick) or vomiting (being sick), loss of appetite or generally feeling unwell, itching, fever, yellowing of the skin and eyes or dark coloured urine
- flushing or marks on your skin that look like targets
- unexplained hair loss
- diarrhoea
- impotence
- breast tenderness and/or breast enlargement
- breast discharge

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 label. 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 the pack and other information

What Zantac contains:

- The active substance is ranitidine (as hydrochloride)
- The other ingredients are hydroxypropyl methylcellulose, ethanol, propyl hydroxybenzoate, butyl hydroxybenzoate, potassium dihydrogen, orthophosphate, disodium hydrogen orthophosphate, sodium chloride, saccharin sodium, sorbitol solution, mint flavour, purified water.
- Each 10 ml dose contains 7.5% w/v ethanol (alcohol) i.e. up to 800 mg per dose.

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.

Marketing Authorisation Holder and Manufacturer

Product licence held by Glaxo Wellcome UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

Manufactured by Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany.

The information provided applies only to Zantac Syrup.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Zantac Syrup**

Reference number 10949/0108

This is a service provided by the Royal National Institute of Blind People.

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