

ZANTAC TABLET

Ranitidine (150 mg, 300 mg)

ZANTAC SYRUP

Ranitidine (150mg/10ml)

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What ZANTAC is used for

Adults/Adolescents (12 years and over)

ZANTAC is used for:

- Stomach and small bowel ulcer that is associated with non-steroidal anti-inflammatory agents (painkillers)
- Small bowel ulcer with *Helicobacter pylori* (bacteria) infection in the stomach
- Post-operative ulcer
- Symptom relief in reflux disease including esophagus inflammation
- Zollinger-Ellison Syndrome (excess acid production in the stomach caused by growth in the pancreas)
- Chronic impaired digestion, characterised by heartburn or epigastric pain which is related to meals or disturbs sleep but not associated with the above conditions
- Prevention of stress ulceration in seriously ill people
- Prevention of recurrent bleeding from stomach ulcer
- Prevention of Mendelson's syndrome (aspiration of gastric contents in pregnant women)

How ZANTAC works

ZANTAC belongs to a group of medicines called H₂-receptor blockers. It works by reducing the amount of acid produced in your stomach.

Before you use ZANTAC

- When you must not use it

Don't take ZANTAC if you are allergic (*hypersensitive*) to ranitidine or any other ingredients of ZANTAC. If you think this applies to you, don't take ZANTAC until you have checked with your doctor.

- Before you start to use it

Before you take ZANTAC, your doctor needs to know:

- If you have stomach cancer
- If you have kidney disease, your doctor may lower your dose of ZANTAC
- If you have a rare condition called acute porphyria
- If you are over 50 years old
- If you have lung disease
- If you are diabetic
- If you have any problems with your immune system
- If you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines

Check with your doctor if you think any of these may apply to you.

If you are pregnant, or think you could be, or if you are planning to become pregnant, don't take ZANTAC without checking with your doctor. Your doctor will consider the risks and benefits to you and your baby of taking ZANTAC.

The ingredients in ZANTAC can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take ZANTAC.

Syrup

ZANTAC Syrup contains ethanol (alcohol). Each 5 ml spoonful contains approximately 400 mg of alcohol which is equivalent to about one spoonful (5 ml) of wine or two

spoonfuls (10 ml) of beer. You may be at risk of side effects if you:

- Are pregnant or breast-feeding
- Have liver disease, epilepsy, or have had an injury to your brain or other condition affecting your brain
- Are an alcoholic

Children may be at higher risk of side effects.

Check with your doctor or pharmacist that ZANTAC Syrup is suitable for you.

ZANTAC contains a small amount of sodium. If you are on a sodium restricted diet, check with your doctor that ZANTAC is suitable for you.

- Taking other medicines

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines bought without a prescription. Some medicines can affect how ZANTAC works, or make it more likely that you'll have side effects. ZANTAC can also affect how some other medicines works. These include:

- Procainamide or n-acetylprocainamide (used to treat heart problems)
- Warfarin (used to thin the blood)
- Triazolam (used to treat sleeping difficulty)
- Glipizide (used to lower blood glucose)
- Midazolam (a sedative that may be given just before an operation)
- Ketoconazole (used to treat fungal infections)
- Atazanavir or delaviridine (used to treat HIV)
- Gefitinib (used to treat lung cancer)
- Non-Steroidal Anti-Inflammatory (NSAID) medicines (used to treat pain and inflammation)

- Sucralfate (used to treat duodenal ulcers)

Tell your doctor or pharmacist if you are taking any of the above.

How to use ZANTAC

- How much to use

Adults

The usual dose is either:

- 150 mg in the morning and 150 mg in the evening or,
- 300 mg at bedtime

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

Tablets

Swallow each tablet whole with some water

Syrup

Use the spoon provided to carefully measure the dose needed. Do not mix ZANTAC Syrup with anything (not even water) before swallowing it.

- When to use it

Always take ZANTAC exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

- How long to use it

It is important that you take the full course of ZANTAC. Don't stop too early, even if you begin to feel better. If you don't complete the full course, the treatment might not be effective and your symptoms may come back.

- If you forget to use it

If you forget a dose, take it as soon as you remember it, unless it is nearly time for your next dose. Don't take a double dose.

- If you use too much (overdose)

If you take too much ZANTAC, contact your doctor or pharmacist for advice. If possible, show them the ZANTAC pack.

While you are using it

- Things you must do

Always take ZANTAC exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

- Things you must not do

This medicine has been prescribed for you or your child personally. Don't pass it on to other people – it may harm them even if their symptoms seem to be the same.

- Things to be careful of

Conditions you need to look out for
Severe allergic reaction: These are rare in people taking ZANTAC. Symptoms 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.

Symptoms 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.

Side Effects

Like all medicines, ZANTAC can cause side effects, but not everybody gets them.

Rare side effects

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

- Allergic reactions
- Skin rash

Rare side effects that may show up in your blood tests:

- 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 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.

Very rare side effects that may show up in your blood tests:

- 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

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of ZANTAC

- Storage

Keep out of the reach and sight of children. Do not use ZANTAC after

the expiry date shown on the pack.
Store ZANTAC Syrup at a dry place below 25°C. Store ZANTAC tablets at a dry place below 30°C.

- Disposal

If you have any unwanted ZANTAC, don't dispose of it in your waste water or household rubbish. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like

Tablets

150 mg:

- White, round, film-coated tablet engraved 'ZANTAC 150' on one face and 'GLAXO' on the other.
- Double foil blister pack. Each carton contains 60 tablets.

300mg:

- White, capsule-shaped, film-coated tablet engraved 'ZANTAC 300' on one face and 'GLAXO' on the other.
- Double foil blister pack. Each carton contains 30 tablets.

Syrup

Peppermint flavoured, sugar free syrup, free from artificial colouring.

- Ingredients

- Active ingredient(s)

Each ZANTAC tablet contains either ranitidine 150mg or 300mg.

Each 10ml of ZANTAC Syrup contains ranitidine 150mg.

- Inactive ingredient(s)

Tablets:

Tablet core:

Microcrystalline cellulose, Croscarmellose sodium (300 mg tablet only), Magnesium stearate

Film coat:

Opadry white OY-S-7322
Purified water

Syrup

Hydroxypropyl methylcellulose 2906 or 2910 (4000 cP), Ethanol (96 percent), Propyl hydroxybenzoate, Butyl hydroxybenzoate, Potassium dihydrogen orthophosphate, Disodium hydrogen orthophosphate anhydrous, Sodium chloride, Saccharin sodium, Sorbitol 70 per cent (Non-crystallising), Mint flavour IFF 17:42:3632, Purified water

- MAL numbers

Zantac Tablet 150mg

- MAL198781471AZ

Zantac Tablet 300mg

- MAL19940613ASZ

Zantac Syrup 150mg/10ml

- MAL19910829ACZ

Manufacturer

Zantac Tablet 150mg

GlaxoSmithKline (Tianjin) Co. Ltd.
No. 65, Fifth Avenue Teda Tianjin,
China

Zantac Tablet 300mg

GlaxoSmithKline Australia Pty Ltd,
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Zantac Syrup

Aspen Bad Oldesloe Gmbh
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Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn.
Bhd.

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