

Package Leaflet: Information for the User

Zantac® Tablets 150 mg and 300 mg

ranitidine hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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, or 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 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.

Take special care with Zantac

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 delavirdine, 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 or pharmacist 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 or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

3 How to take Zantac Tablets

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.
 - Swallow each tablet whole with a glass of water.
- The usual dose for an adult (including the elderly) and adolescents (12 years and over) 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.

Children over 30 kg of weight and from 3 to 11 years:

Your doctor will work out the right dose for you based on your child's weight.

Treatment of stomach or duodenal (small intestine) 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 many tablets 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 tablets you should start to feel much better. Do not stop taking the tablets 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, Zantac 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 a sign of something called 'pancreatitis'
- a slow or irregular heartbeat

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

Common (affects less than 1 in 10 people)

- headache (sometimes severe)
- feeling dizzy
- diarrhoea.

Uncommon (affects less than 1 in 100 people)

- having blurred vision
- a rash on its own.

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

Very rare (affect less than 1 in 10,000 people)

- false results in blood tests called 'liver function tests'
- feeling depressed.

During post-marketing experience, the following have been reported (unknown frequency):

- 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 confused, seeing or hearing unexplained things (hallucinations)
- 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
- impotence
- breast tenderness and/or breast enlargement
- breast discharge.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 How to store Zantac

- Keep out of the reach and sight of children.
- Do not use Zantac after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Zantac contains:

- The active substance is ranitidine (as the hydrochloride) 150 mg or 300 mg
- The other ingredients are microcrystalline cellulose, magnesium stearate, methylhydroxypropyl cellulose, titanium dioxide (E171) and triacetin. 300 mg tablets also contain croscarmellose sodium.

What Zantac looks like and contents of the pack

Zantac Tablets 150 mg are round, white tablets.

Zantac Tablets 300 mg are white, capsule-shaped tablets.

Cartons contain aluminium foil strips or push through double foil blisters. 150 mg strength cartons contain 60 tablets in strips of 10 and 300 mg strength cartons contain 30 tablets in strips of 5.

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Manufactured by Glaxo Wellcome GmbH & Co KG, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

The information provided applies only to Zantac Tablets 150 mg and 300 mg

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 Tablets 150 mg**
 Zantac Tablets 300 mg

Reference number 10949/0042

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

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