

Zantac® 300mg Film-coated Tablets

ranitidine (as hydrochloride)

Patient Information Leaflet

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 Tablets
- 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 some times 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 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 (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 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 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
- * 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 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 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.

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:

- * 150mg in the morning and 150mg in the evening, or
- * 300mg at bed time.

A maintenance dose of 150 mg at night may be used. In certain cases treatment may be given at a higher dose, up to 600mg (300mg twice daily) and may last 8-12 weeks. Zantac 150mg tablets are also available to enable the different dosing schedules. Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Use in children over 30kg of weight and from 3 to 11 years:

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

Other forms of this medicine may be more suitable for children; ask your doctor or pharmacist.

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 to a maximum dose of 300 mg per day. Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

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Patient Information Leaflet (continued)

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 of 600 mg 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 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 medicine, 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 HPRAs 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 this medicine

- * Keep out of the sight and reach of children
- * Do not use this medicine after the expiry date which is stated on the blister and on the carton after "exp". The expiry date refers to the last day of that month.
- * Do not store above 30°C.
- * 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 this pack and other information

What Zantac contains:

- * The active substance is ranitidine (as the hydrochloride) 300 mg

The other ingredients are: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, hypromellose, titanium dioxide (E171) and triacetin.

What Zantac looks like and contents of the pack

Zantac 300mg are white, round tablets engraved 'GXEC3' on one side and plain on the other side.

Each pack contains 30 film-coated tablets. For oral administration.

* The Parallel Product Authorisation is

The Parallel Product Authorisation Holder: LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

* Repackaged by

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

* The Manufacturer is:

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

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Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: + 44 (0)1527 505414 for help.