

Ranitidine

Zantac₇₅[®] 75mg Tablet H₂-Antagonist

Patient Information Leaflet

What you should know about Ranitidine (Zantac₇₅[®]) 75mg Tablets

This leaflet only talks about Ranitidine (Zantac₇₅[®]) 75mg Tablets. Please read it carefully before you start to take your medicine. It tells you the main points about the medicine. For more information or advice ask your doctor or pharmacist.

What is in your medicine

Each tablet contains 75mg Ranitidine (as the hydrochloride)

How your medicine works

The stomach contains hydrochloric acid which helps to digest your food.

Sometimes your stomach produces too much acid. This excess acid can lead to the conditions known as heartburn and dyspepsia (acid indigestion).

Ordinary antacid remedies contain ingredients which simply neutralise this acid. Their effect is short lived and you may need to take them regularly to keep your symptoms under control.

What is your medicine used for

Ranitidine (Zantac₇₅[®]) 75mg Tablets are a completely different way of treating the problems of heartburn, excess acid and dyspepsia (acid indigestion). If these problems are usually related to eating and drinking they can be prevented by taking Ranitidine (Zantac₇₅[®]) 75mg Tablets half to one hour before food/drink. Instead of just neutralising the excess acid, they work on the source of the problem by preventing your stomach from producing too much acid in the first place. One Ranitidine (Zantac₇₅[®]) 75mg Tablets starts working within 30 minutes and can control excess acid for at least 12 hours to bring you rapid and long lasting relief during the day or at night.

How to take your medicine

Adults (including the elderly) and children 16 years of age and older

To prevent symptoms occurring:

Swallow one Ranitidine (Zantac₇₅[®]) 75mg Tablets whole, with a drink of water, half to one hour before eating and drinking.

To treat symptoms already present:

Swallow one Ranitidine (Zantac₇₅[®]) 75mg Tablets whole with a drink of water, as soon as you have symptoms, at any time, day or night. Most people will find one or two tablets per day sufficient, however up to four tablets may be taken in a 24 hour period.

Children under 16 years: Ranitidine (Zantac₇₅[®]) 75mg Tablets are not recommended for children under 16 years of age.

Before you take your medicine

Please get your doctor or pharmacist's advice before taking these tablets:

- If you are allergic to ranitidine or any of the ingredients of Ranitidine (Zantac₇₅[®]) 75mg Tablets
- If you have been told you have a peptic ulcer ("stomach" or "duodenal")
 - o Patients who are taking non-steroidal anti-inflammatory drugs especially in those with a history of peptic ulcer
- If you are pregnant, trying to become pregnant or breast-feeding
 - o Ranitidine crosses the placenta and is excreted in human breast milk
- If you have kidney or liver problems
- If you suffer from a rare condition called porphyria
 - o Rare clinical reports suggest that ranitidine may precipitate acute porphyric attacks
- If you have unintended weight loss associated with dyspepsia (acid indigestion)
- If you are middle aged or older and have dyspeptic (acid indigestion) symptoms for the first time or symptoms that have recently changed
- If you have any other illness, are taking any medicines either prescribed by your doctor or bought from your pharmacist or elsewhere, or seeing a doctor regularly
- If you are undergoing treatment with a histamine H₂ – antagonist (may mask symptoms associated with carcinoma of the stomach an may therefore delay diagnosis of the condition)
- Patients with renal impairment (creatinine clearance less than 50mL/min) and/or hepatic impairment
 - o Ranitidine is excreted via the kidney and so plasma levels of the drug are increased in patients with renal impairment (creatinine clearance less than 50mL/min.). Ranitidine products are not suitable for these patients without medical supervision
- Patients under regular medical supervision
- Patients taking medications either physician prescribed or self prescribed

Side Effects

Most people taking this medicine find that it causes no problems. As with all medicines, allergic reactions may occur rarely.

So if you have the following symptoms soon after taking Ranitidine (Zantac75®) 75mg Tablets, STOP the tablets and tell your doctor immediately.

- Sudden wheeziness and chest pain or chest tightness
- Swelling of eyelids, face, lips, mouth or tongue
- Lumpy skin rash or "hives" anywhere on the body
- Unexplained fever
- Feeling faint, especially on standing up

You should also stop taking the tablets and consult your doctor if you suffer recurrent infection or unexpected bruising.

Side effects have been rare, if however you experience any of the following, tell your doctor or pharmacist.

- Confusion
- Nausea and loss of appetite, which are worse than normal and/or jaundice (yellow colouring of the skin or the whites of the eyes) as this may be due to hepatitis (inflammation/infection of the liver). Slow or irregular heartbeat, dizziness, tiredness or fainting
- Blurred vision
- Skin reaction, occasionally severe (red/purple spots or rash)
- Hair loss
- Impotence
- Severe stomach pain or a change in the type of pain
- Diarrhoea
- Breathlessness and fatigue
- Headache
- Dizziness
- Joint or muscle pains
- Changes in the amount of urine passed its colour, nausea, vomiting, confusion, fever and rash as these may be due to kidney problems
- Feeling of depression
- Hallucinations
- Abnormal muscular body movements or shaking
- If you are a man – breast tenderness and/or breast enlargement

Tell your doctor that you are taking Ranitidine (Zantac75®) 75mg Tablets if you have a blood, urine or other test as the medicine may affect the result. There are no data on the effects of ranitidine on human fertility.

If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

What are the drugs that interact with your medicine

Ranitidine has the potential to affect the absorption, metabolism or renal excretion of other drugs. The altered pharmacokinetics may necessitate dosage adjustment of the affected drug or discontinuation of treatment.

Interactions occur by several mechanisms including:

- Inhibition of cytochrome P450-linked mixed function oxygenase system: Ranitidine at usual therapeutic doses does not potentiate the actions of drugs which are inactivated by this enzyme: diazepam, lidocaine, phenytoin, propranolol, and theophylline. Reports of altered prothrombin time with coumarin anticoagulants (e.g. warfarin). Due to narrow therapeutic index, close monitoring of increased or decreased prothrombin time is recommended during concurrent treatment with ranitidine
- Gastric pH alteration: bioavailability of certain drugs may be affected, may result to either increase in absorption (e.g. triazolam, midazolam, glipizide) or a decrease in absorption (e.g. ketoconazole, atazanavir, delavirdine, gefitinib)

What to do if you take too much

If you accidentally take many more tablets than recommended, contact your doctor or pharmacist.

After taking your medicine

You should find that these tablets prevent and/or relieve your symptoms.

If your symptoms are no better, get worse or continue for two weeks after taking regular treatment, then consult your doctor or pharmacist.

Further Information

How can I avoid heartburn, excess acid and dyspepsia (acid indigestion)?

A number of factors may contribute towards people suffering heartburn, excess stomach acid and dyspepsia (acid indigestion).

- Over eating

- Poor diet (too much fatty food)
- Being overweight
- Lack of exercise
- Smoking
- Excessive alcohol intake

If at all possible it is best to moderate your life style where each of these factors is concerned to ensure you have the best possible chance of avoiding heartburn, excess stomach acid and dyspepsia (acid indigestion).

Not all information about your medicine is printed here. If, after reading this leaflet, you have any questions or are not sure about anything, ask your pharmacist.

Patients are advised to consult their doctor or pharmacist if symptoms persist, get worse or continue for 14 days.

Storing your medicine

Store at temperatures not exceeding 30°C. Keep dry. Protect from light.

Caution

Keep all medicines out of reach of children.

YOU MAY WANT TO READ THIS LEAFLET AGAIN. PLEASE DO NOT THROW IT AWAY UNTIL YOU HAVE FINISHED YOUR MEDICINE.

ZANTAC₇₅ is a registered trademark of the GlaxoSmithKline group of companies.

©2012, GlaxoSmithKline. All rights reserved.

Version Number: GDS v.9 Revision Date: 12 April 2012



Imported by:

GlaxoSmithKline Philippines Inc

2266 Chino Roces Avenue, City of Makati 1231

Tel. 892-0761

Manufactured by:

GlaxoSmithKline (Tianjin) Co. Ltd.

65 Fifth Avenue Teda Tianjin 300457

The People's Republic of China