Package leaflet: Information for the user

ZANTAC 75, 75 mg tablets

The active substance in Zantac 75 is ranitidine hydrochloride, corresponding with 75 mg ranitidine.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What Zantac 75 is and what it is used for

Zantac 75 tablets are one of a group of medicines known as histamine H_2 antagonists. H_2 antagonists temporarily reduce the production of acid in the stomach, to remove the cause of heartburn and acid indigestion. Enough acid remains to help digestion.

You can take Zantac 75 tablets when you suffer from complaints caused by stomach acid, such as heartburn and acid indigestion.

2. What you need to know before you take Zantac 75

Do not take Zantac 75
- if you are allergic to ranitidine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Take special care with Zantac 75 if you
- have a severe kidney or liver disorder.
- undergo regular medical examinations.
- are middle-aged or older and suffer stomach complaints for the first time, or if your complaints worsen.
- take medicines on or without prescription.
- have stomach complaints and are losing weight unintended.

– take non-steroidal anti-inflammatory painkillers (NSAIDs, e.g. aspirin or ibuprofen), especially if you have had a stomach ulcer in the past.
– have ever experienced an acute porphyria (a congenital disorder in the production of the red blood pigment heme).
– are elderly.
– have breathing problems.
– have a weak immune system.
– suffer from diabetes.

Talk to your doctor or pharmacist before taking Zantac 75.

Screening tests:
The use of ranitidine may result in unreliable (false positive) urine screening tests used to detect amphetamine and methamphetamine. Additional tests to confirm the results may be necessary.

Children
The use of Zantac 75 in children under 16 years of age is not recommended.

Other medicines and Zantac 75
Zantac may affect other medicines which you are taking.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription, particularly if you take medicines:

- to prevent blood clotting (e.g. warfarin)
- to resist infections (e.g. ketoconazole, atazanavir or delaviridine)
- to control your blood sugar (e.g. glipizide)
- to treat anxiety and sleeping disorders (e.g triazolam, midazolam)
- to treat certain types of cancer (e.g. gefitnib)

Zantac 75 with food and drink
You can take Zantac 75 at any time, with or without food and drink.

Pregnancy, breast-feeding and fertility
Ranitidine passes the placenta and is secreted in breast milk. For that reason, you must not take Zantac 75 tablets while you are pregnant or breast-feeding without consulting a doctor first.
There are no human data on the effect of ranitidine on fertility. In animal studies, no effect on fertility was observed.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Insufficient data on the effects on ability to drive and to operate machines is available.

3. How to take Zantac 75

As soon as you have heartburn or acid indigestion, whether it is during the day or at night, you can take one tablet. Zantac 75 produces a long-term effect that starts around 30 minutes after taking the tablet. The effect reaches its peak after two hours and can last for up to twelve hours. This is why most patients need no more than one or two tablets every 24 hours. However, if needed, you may take up to maximum four tablets per 24-hour period.
Do not exceed the recommended dose.

You can swallow a Zantac 75 tablet with some liquid.

Children under 16:
Zantac 75 is not intended for use by children under 16.

Reduced kidney function:
If you have kidney problems, you must see your doctor before use as your dose may need to be changed.

If you take more Zantac 75 than you should
If you take more Zantac 75 than you should, you must contact your doctor or pharmacist immediately.

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.

Uncommon side effects (from 1 in every 100 to 1 in every 1,000 patients):
- abdominal pain.
- constipation.
- diarrhoea.
- nausea.

These symptoms mostly improved during continued treatment.

Rare side effects (from 1 in 1,000 to 1 in 10,000 patients):
– hypersensitivity reactions (rashes with intense itching and lumps (hives or urticaria), sudden accumulation of fluid in the skin and mucus membranes (such as the throat or tongue), breathing difficulties and/or itching and rash, often as an allergic reaction (angioneurotic oedema), fever, tightness of the chest due to cramps in the airway muscles (bronchospasm), low blood pressure (hypotension) and chest pain).
– skin rash.

Very rare side effects (less than 1 in 10,000 patients):
– certain blood disorders such as leucopenia (a lack of white blood cells, accompanied by increased susceptibility to infections), thrombocytopenia (a lack of blood platelets, accompanied by bruises and a proneness to bleeding). Pancytopenia (a general lack of blood cells) or agranulocytosis, (a very serious shortage of white blood cells which is accompanied by sudden and high fever, a severely sore throat and ulcers in the mouth), sometimes with marrow hypoplasia (a condition where the bone marrow is not forming

properly) or marrow aplasia (a disorder in which the bone marrow does not produce sufficient new cells).
- Anaphylactic shock (a sharp fall in blood pressure, pallor, anxiety, weak and fast pulse, clammy skin, reduced consciousness) caused by a sudden and considerable widening of the blood vessels due to serious hypersensitivity to specific substances).
- depression, hallucinations and reversible mental confusion. These have been reported mainly among severely ill and elderly patients.
- Headache (sometimes severe), dizziness and reversible involuntary movement disorders.
- reversible blurred vision.
- slow heart beat (bradycardia).
- certain disorders in the conduction system of the heart, leading to heart rhythm disorders (AV block).
- inflammation of a blood vessel (vasculitis).
- acute inflammation of the pancreas (acute pancreatitis).inflammation of the liver (hepatitis), which is generally reversible and may be combined with jaundice (yellowish discoloration of the skin or eyes).
- itch (pruritis)
- rash with red and irregular (moist) patches (erythema multiforme).
- hair loss (alopecia).
- pain in the muscles or joints.
- inflammation of the kidneys, accompanied by blood in the urine, fever, and pain in the side (interstitial nephritis).
- reversible impotence.
  development of abnormally large mammary glands in males resulting in breast enlargement (gynaecomastia) and spontaneous flow of milk from the breast, unassociated with childbirth or nursing (galactorrhoea).

Reporting of 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 the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zantac 75

Store in the original package in order to protect from light and/or moisture, below 25°C.

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 after “Do not use after”. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Zantac 75 contains
- The active substance is ranitidine (in the form of ranitidine hydrochloride).
- The other ingredients are microcrystalline cellulose, magnesium stearate, hypromellose, titanium dioxide (E171), triacetin, and synthetic red iron oxide (E172).

What Zantac 75 looks like and contents of the pack
Zantac 75 is a medicine in the shape of a pentagonal pink-coated tablet. On the one side of each tablet is the letter “Z”, and on the other side “75”.
The tablets come in blister packs. One pack of Zantac 75 contains 12, 24 or 48 tablets.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
to be completed nationally

Manufacturers:
to be completed nationally

This leaflet was last revised in