

Zantac® 150mg Film Coated Tablets

ranitidine (as hydrochloride)

• What you should know about Zantac 150mg Film Coated Tablets

This leaflet talks only about Zantac 150mg Film Coated Tablets. Please read it carefully before you start to take your medicine and keep it until you have finished your medicine. It tells you the main points about your medicine. For more information or advice ask your doctor or pharmacist.

• The name of your medicine

The name of your medicine is Zantac 150mg Film Coated Tablets ranitidine (as hydrochloride).

• What is in your medicine?

Each white, round film-coated tablet contains 150mg of the active ingredient ranitidine (as the hydrochloride). The other ingredients are: microcrystalline cellulose (E460), magnesium stearate, hypromellose (E464), titanium dioxide (E171) and triacetin.

Each pack contains 60 tablets.

• How your medicine works

Zantac 150mg Film Coated Tablets contain ranitidine, one of a group of medicines called H₂ antagonists. This group of medicines reduces the amount of acid produced in your stomach.

• What are Zantac 150mg Film Coated Tablets used for?

Your doctor has chosen this medicine to suit you and your condition. Zantac 150mg is prescribed for the following reasons:

For adults (including the elderly) Zantac is taken for the following:

- To heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- To stop stomach ulcers when they are a side effects of some medicines
- To 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 'gastro-oesophageal reflux' 'indigestion', 'dyspepsia' or 'heartburn'
- To stop acid coming up from the stomach while under anaesthetic during an operation
- To prevent ulcers from bleeding
- To treat other conditions where reduction of acid in the stomach is likely to be beneficial

For Children 3 to 18 years

- For the short term treatment of ulcers in the stomach, or the part of the gut that it empties into (the duodenum)
- To 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 'gastro-oesophageal reflux' 'indigestion', 'dyspepsia' or 'heartburn'

• Before you take your medicine

If you answer "Yes" to any of the following questions, tell your doctor about this before taking this medicine

- Have you been told that you are allergic to Zantac, ranitidine or any of the other ingredients in Zantac 150mg Film Coated Tablets?
- Do you have kidney disease or have you been told that your kidneys are not working properly?
- Do you have a rare condition called porphyria?
- Are you pregnant, or trying to become pregnant?
- Are you breast-feeding?
- Have you had unintended weight loss associated with dyspepsia (acid indigestion)?
- Are you middle aged or older and have you had dyspeptic (acid indigestion) symptoms for the first time or symptoms that have recently changed?
- Are you taking medicines to treat any of the following conditions: irregular heart beat (e.g. procainamide, **N-acetyl procainamide**), resist infections (e.g. ketaconazole, atazanavir or **delaviridine**), diabetes (e.g. glipizide), anxiety (e.g. **triazolam**, midazolam) **chemotherapy treatment (e.g. gefitinib)** or using anticoagulants (medicines to thin your blood e.g. warfarin).

Make sure that your doctor knows what other medicines you are taking, including any which you bought yourself. You should see your doctor regularly especially if you are taking Zantac Tablets as well as medicine for arthritis. This is particularly important in the elderly or those with a history of ulcers.

• How to take your medicine

Take your medicine as your doctor has told you. The label on it will tell you how much to take and how often. If you are not sure ask your doctor or pharmacist. Swallow each tablet whole with a drink of water.

Adults (including elderly) and Adolescents (12 years and over):

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.

This may be increased 300mg twice daily. It is important that you keep taking the medicine until you finish the full course of treatment prescribed. Even when you feel better your doctor may decide to continue your treatment with Zantac Tablets in order to prevent the pain and discomfort from returning. A maintenance dose of 150mg at night may be used.

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

If prescribed for a child, your doctor will work out the right dose based on your child's weight.

Treatment of stomach or duodenal ulcers:

- 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. Each dose should be taken about 12 hours apart. The duration of treatment for stomach and duodenal ulcers may be increased to 8 weeks.

Treatment of gastro-oesophageal reflux:

- 2.5 mg to 5mg for each kg of body weight twice a day to a maximum dose of 600 mg per day.

It is important that your child keeps taking the medicine until the full course of treatment prescribed is finished.

• **What to do if you take too many**

It is important to keep to the dose on the label of your medicine. Taking more than this is unlikely to be dangerous unless many tablets are taken at once. In that case, don't delay; ask your doctor what to do or contact your nearest hospital emergency department.

• **What to do if you miss a dose**

If you forget to take a dose, take another as soon as you remember. Then go on as before.

• **After taking your medicine**

After a few days you should feel much better but don't stop taking the tablets or the pain and discomfort may return. Most people taking this medicine find that it causes no problems. As with all medicines, a few people may find that it causes side effects.

A few people can be allergic to some medicines; if any of the following side-effects come on soon after taking these 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

Also check with your doctor as soon as possible if any of these uncommon side-effects are noticed:

- 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 heart beat
- 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
- Unusual tiredness, shortness of breath or tendency to infections or bruising, which can be caused by upsets to 'blood counts'
- Diarrhoea

Also check with your doctor at your next visit if any of these side-effects are noticed:

- Headache
- Dizziness
- Joint or muscle pains
- Kidney problems (symptoms may include change in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash).
- Feeling of depression
- Hallucinations
- Abnormal muscular body movements or shaking
- If you are a man - breast tenderness and/or breast enlargement.

If you are unwell or have any unusual discomfort you do not understand, tell your doctor.

• **Storing your medicine**

Do not take the tablets after the expiry date as shown on the over labelled carton and blister foil.
Do not store above 30°C.

Keep all medicines out of the reach and sight of children.

Return any unwanted tablets to your pharmacist for destruction.

• **Remember**

This medicine is for you or your child. Never give it to someone else. There may be reasons why it could harm that person.

• **Further information**

This leaflet does not tell you everything about your medicine. If you have any questions or are not sure about anything, then ask your doctor or pharmacist.

You may need to read this leaflet again. Please do not throw it away until you have finished your medicine.

The information provided applies only to Zantac 150mg Film Coated Tablets

• **Who has made your medicine?**

Zantac 150mg Film Coated Tablets are manufactured by Aspen Bad Oidesloe GmbH, Industriestrasse 32-36, 23843 Bad Oidesloe, Germany.

Procured from within the EU by the parallel product authorisation holder McDowell Pharmaceuticals, 4 Altona Road, Lisburn, N. Ireland, BT27 5QB, and repackaged by: Amimed Direct Ltd., Unit 20, Garrick Ind. Est., Irving Way, Hendon, London NW9 6AQ, UK.

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