

PACKAGE LEAFLET: INFORMATION FOR THE USER

Zabcid Tablets 200mg, 400mg and 800mg

[Cimetidine]

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Zabcid Tablets are and what they are used for
2. What you need to know before you take Zabcid Tablets
3. How to take Zabcid Tablets
4. Possible side effects
5. How to store Zabcid Tablets
6. Contents of the pack and other information

1. WHAT ZABCID TABLETS ARE AND WHAT THEY ARE USED FOR

Zabcid Tablets belong to a group of medicines called *H2-receptor antagonists* which act to decrease the natural production of acid in the stomach.

Zabcid Tablets have been prescribed to treat any of the following:

- Ulcers in the stomach (gastric ulcer) or in the upper part of the intestine (duodenum ulcer)
- Acid from the stomach escaping into the food pipe causing pain, inflammation and heartburn (oesophageal reflux disease)
- Excess acid in the stomach caused by a tumor in the pancreas (Zollinger-Ellison syndrome)
- Ulcers in the stomach or duodenum which may be caused by non-steroidal anti-inflammatory drugs (NSAIDs), often used to reduce pain, fever and inflammation
- Various conditions where reduction of gastric acid by cimetidine has been shown to be beneficial e.g.
 - Indigestion symptoms (e.g. stomach pain or discomfort, heartburn)
 - Meal-related upper abdominal pain
 - To prevent stress ulcers from bleeding
 - To be given before general anaesthesia to prevent damage to the lungs caused by breathing in stomach fluids (acid aspiration)
 - To improve absorption of food and reduce fluid loss in short bowel syndrome
 - Reduction of breakdown of pancreatic enzyme supplements.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZABCID TABLETS

Do not take Zabcid Tablets:

- If you are hypersensitive (allergic) to cimetidine or any of the other ingredients of Zabcid Tablets (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Zabcid Tablets if you:

- Suffer or have suffered in the past from kidney disease
- Have a history of peptic ulcer, particularly if you are taking a non-steroidal anti-inflammatory drug (NSAID) e.g. aspirin, ibuprofen, naproxen, diclofenac
- Are taking drugs or you have an illness that could cause a fall in blood cell count
- Are middle aged or over, with new or recently changed indigestion symptoms (e.g. stomach pain or discomfort, heartburn), then other causes of your symptoms such as stomach cancer, should be excluded

- Are taking other medicines (see Section 'Other medicines and Zabcid Tablets').

Other medicines and Zabcid Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor if you are taking any of the following:

- Anticoagulants to thin your blood e.g. warfarin
- Anticonvulsants to prevent fits e.g. phenytoin
- Bronchodilators for breathing difficulties e.g. theophylline
- Anti-arrhythmics to slow heart rate e.g. lidocaine, propranolol
- Antidepressants to treat anxiety e.g. diazepam
- Immunosuppressants to prevent organ rejection or rheumatism (e.g. ciclosporin)
- Medicines that cause a fall in blood cell count
- Antifungals used to treat fungal infections (e.g. ketoconazole, itraconazole or posaconazole)
- Antidiabetics to lower glucose levels in the blood (e.g. metformin or glipizide)
- Anti-cancer drugs for the treatment of cancer or tumors (e.g. carmustine, fluorouracil, epirubicin, or therapies such as radiation)
- Strong pain killers (e.g. morphine)
- Antiretroviral drugs used to treat HIV/AIDS (e.g. atazanavir)
- Tacrolimus used to treat eczema
- Medicines to treat heart problems e.g. diltiazem, procainamide, metoprolol.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice if you are pregnant, planning on becoming pregnant or are breast-feeding. The use of cimetidine during pregnancy and breast-feeding should be avoided unless considered essential by your doctor.

Driving and using machines

These tablets can cause some people to feel dizzy or drowsy. If you are affected do not drive or operate machinery.

3. HOW TO TAKE ZABCID TABLETS

Always take Zabcid Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dosage is 400mg to 1600mg cimetidine per day. Take twice a day with breakfast and at bedtime or as directed by your doctor.

Do not take more than 2400mg cimetidine per day.

Elderly:

The normal adult dosage may be used unless you have kidney problems.

Patients with duodenal or gastric ulceration:

A single dose of 800mg at bedtime is recommended. Although your doctor may recommend 200mg three times a day with meals and 400mg at bedtime.

Patients with oesophageal reflux disease:

400mg four times a day with meals and at bedtime is recommended.

Patients with Zollinger-Ellison syndrome:

400mg four times a day with meals and at bedtime is recommended. Higher doses may be given.

Patients with acid aspiration:

A dose of 400mg can be given 90-120 minutes before having a general anaesthetic or, in obstetric practice, at the start of labour. While there is still a risk of acid aspiration, a dose of up to 400mg may be repeated at 4 hourly intervals, as required, up to the usual daily maximum of 2.4g.

Prevention of bleeding from stress ulcers in seriously ill patients:

200-400mg can be given every 4-6 hours.

Patients with kidney problems:

Doses may be reduced but your doctor will advise you on the amount to take.

If you take more Zabcid Tablets than you should

This medicine is to be taken at regular intervals, as determined by the physician. If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you.

If you stop taking Zabcid Tablets

You may feel better after a few days, but you should keep taking your tablets until the prescribed course is finished. Your symptoms may come back if you stop your treatment too soon.

If you forget to take Zabcid Tablets

If you have forgotten to take a dose, leave out that dose completely. Take your next dose at the normal time. If you have trouble remembering to take the tablets, tell your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Allergic reactions may occur rarely, with symptoms such as rash, itching, swelling of the face, wheeziness, shortness of breath, tightness in the chest, fever, low blood pressure and feeling dizzy particularly when standing up. **If any of these occur STOP taking the medicine and contact a doctor immediately.**

Common side effects (affects 1 to 10 users in 100):

- Headache
- Dizziness
- Diarrhoea
- Skin rashes
- Myalgia (muscle aches)
- Tiredness.

Uncommon side effects (affects 1 to 10 users in 1,000):

- Leukopenia - decrease in the number of white blood cells
- Depression
- Confusion (usually in the elderly or seriously ill)
- Hallucinations (hearing and seeing things that are not there)
- Tachycardia (fast heartbeat)
- Liver disorder (hepatitis) stomach and abdomen tenderness, loss of appetite, with or without jaundice (yellowing of the whites of the eyes and skin)
- Breast enlargement in men (gynaecomastia) - this is usually reversible when the medicine is stopped
- Problems getting and maintaining an erection (impotence).

Rare side effects (affects 1 to 10 users in 10,000):

- Thrombocytopenia - abnormally low number of platelets in the blood
- Aplastic anaemia - bone marrow disorder
- Sinus bradycardia - slow heartbeat
- Increased serum transaminase levels which is reversible when the medicine is stopped
- Kidney disorders (Interstitial nephritis with symptoms such as blood in urine, increased or decreased urine output, nausea and vomiting)
- Small increases in plasma creatinine have been reported.

Very rare side effects (affects less than 1 user in 10,000):

- Pancytopenia - blood disorder with low number of red and white blood cells and platelets
- Agranulocytosis - blood disorders with very low numbers of white blood cells
- Heart block - symptoms may include irregular heartbeats
- Inflammation of the pancreas - symptoms include stomach and back pain, nausea and vomiting
- Hair loss -reversible after treatment has stopped
- Arthralgia - aching muscles and joints
- Galactorrhoea - leakage of a milky substance from the breasts
- Fever.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZABCID TABLETS

Check the expiry date printed on the label or side of the box. Do not use after the expiry date stated on the label.

Do not store above 25°C. Store in the original package.

In case of any visible signs of deterioration, you should discard the package.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

Keep out of the sight and reach of children

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Zabcid Tablets contain:

Zabcid Tablets 200, 400 and 800mg contain the active substance cimetidine 200mg, 400mg or 800mg in each film-coated tablet respectively.

The other ingredients are: Microcrystalline cellulose (E460), povidone 30, sodium starch glycollate, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate, hydroxypropyl methylcellulose (E464), polyethylene glycol, quinoline yellow aluminium lake (E104), indigo carmine aluminium lake (E132), titanium dioxide (E171) and iron oxide yellow (E172).

What Zabcid Tablets look like and contents of the pack

Zabcid 200mg Tablets are pale green, circular, biconvex, film coated tablets, embossed with C1 on one side.

Zabcid 400mg Tablets are pale green, oblong, film coated tablets, embossed with C2 on one side.

Zabcid 800mg Tablets are pale green, oval, film coated tablets, embossed with C3 on one side.

Zabcid 200mg Tablets are packed in cartons containing 12, 24, 48, 60 or 120 tablets in foil blister strips and in polypropylene tubes with pack sizes of 100, 250, 500 and 1000 tablets.

Zabcid 400mg Tablets are packed in cartons containing 60 tablets in foil blister strips and in polypropylene tubes with pack sizes of 100, 250, 500 and 1000 tablets.

Zabcid 800mg Tablets are packed in cartons containing 30 tablets in foil blister strips and in polypropylene tubes with pack sizes of 60, 100, 150, and 250 tablets.

Not all pack sizes may be marketed.

Manufacturer and Marketing Authorisation Holder:

Ennogen Pharma Limited,
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford, DA1 5BS, UK.

This leaflet was last revised in June 2014.