

Cimetidine 200mg/5ml Oral Solution

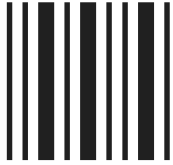
- **Read all of this leaflet carefully before you start taking this medicine**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours

- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



In this leaflet:

1. What is Cimetidine Oral Solution and what is it used for
2. What do you need to know before you take Cimetidine Oral Solution
3. How to take Cimetidine Oral Solution
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1. What is Cimetidine Oral Solution and what is it used for

The name of your medicine is Cimetidine 200mg/5ml Oral Solution. It contains cimetidine. This belongs to a group of medicines called H₂ antagonists, which reduce the amount of acid in your stomach.

This medicine is used to:

- heal and stop ulcers in the stomach, or the part it empties into, the duodenum
- heal and stop problems caused by acid in the gullet (oesophagus) or too much acid in the stomach. This can cause pain or discomfort known as indigestion or heartburn
- prevent ulcers from bleeding
- prevent ulcers which may be caused by medicines called non-steroidal anti-inflammatories (NSAIDs), often used to treat arthritis
- improve absorption of food and reduce fluid loss in short bowel syndrome
- be given before an operation to prevent acid coming up from the stomach whilst under anaesthetic.

2. What do you need to know before you take Cimetidine Oral Solution

Do not take Cimetidine Oral Solution and tell your doctor if:

- you are allergic (hypersensitive) to cimetidine or any other ingredients in this liquid (listed in Section 6 below)

The signs of an allergic reaction include a rash, itching or shortness of breath

- you are pregnant, likely to become pregnant and if you are breast-feeding.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking cimetidine.

Warnings and precautions

Before you take cimetidine, tell your doctor if:

- you have kidney problems
- you have a blood disease
- you have lost weight recently and also have stomach ache, stomach pain or indigestion at the same time, particularly if you are over 40.

You should see your doctor regularly especially if you are taking Cimetidine Oral Solution as well as medicine for arthritis. This is particularly important in the elderly or those with a history of ulcers and are also taking a non-steroidal anti-inflammatory drug (NSAID), (e.g. ibuprofen)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking cimetidine.

Going into hospital

Do not take this medicine if you are going into hospital today for an operation or to give birth.

Other medicines and Cimetidine Oral Solution

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because cimetidine can affect the way some other medicines work. Also some medicines can affect the way cimetidine works.

Tell your doctor if you are taking any of these medicines

- non-steroidal anti-inflammatories (NSAIDs) e.g. indometacin, aspirin
- strong painkillers such as morphine
- phenytoin, used for epilepsy
- tricyclic antidepressants, used to treat depression, such as amitriptyline
- medicines to stop the blood clotting such as warfarin
- medicines that cause a fall in blood cell count
- theophylline, used for asthma
- medicines that lower blood pressure or treat heart conditions (e.g. metoprolol, propranolol, nifedipine, diltiazem, procainamide)
- medicines that numb the body such as anaesthetics used in hospital (e.g. lidocaine)
- medicines that are given after organ transplants to stop the body rejecting the organ such as ciclosporin and tacrolimus
- medicines used to treat HIV/AIDs such as atazanavir
- medicines used to treat fungal infections such as ketoconazole, itraconazole and posaconazole
- medicines to treat cancer such as carmustine, fluorouracil, epirubicin, or therapies such as radiation
- medicines used to treat diabetes such as metformin or glipizide
- medicines that treat anxiety e.g. diazepam.

Pregnancy and breast-feeding

- Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding. Cimetidine should not be used when you are pregnant or breast feeding unless the doctor considers it necessary
- Do not take this medicine if you are in labour.

Driving and using machines

This product should not affect your ability to drive or to use machinery.

Important information about what is in Cimetidine Oral Solution

This medicine contains:

- Methyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine.
 - Liquid maltitol (E965) (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
 - Sorbitol. This medicine contains 200 mg sorbitol (E420) in each 5 ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
 - Propylene glycol. This medicine contains 500 mg propylene glycol (E1520) in each 5 ml.
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant, breast-feeding, suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

- Sunset yellow E110. This may cause an allergic reaction including asthma.
- This medicine contains less than 1 mmol sodium (23 mg) per 1ml, that is to say essentially 'sodium-free'.

3. How to take Cimetidine Oral Solution

Take this medicine as your doctor or pharmacist has told you. Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- This medicine contains 200mg of cimetidine in each 5ml
- Take this medicine by mouth
- The total daily dose should not be more than 2.4g each day
- The usual length of treatment is 4 weeks.

Adults and older people

The usual doses for adults are given below:

- The usual dose is 400mg (two 5ml spoonfuls) at breakfast and at bedtime. This may be altered by your doctor depending upon what this medicine is being prescribed for.

Children above 1 year old

If prescribed for a child, the dosage depends on the child's weight. Make sure the child takes the liquid as the doctor says. The usual dose is 25-30mg/Kg body weight each day. The dose should not be more than 2.4g each day.

People with severe kidney problems

The dose may be lowered if you have kidney problems as you may be more sensitive to the effects of the medicine.

If you take more Cimetidine Oral Solution than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Cimetidine Oral Solution

Do not take a double dose (two doses at the same time) to make up for forgotten doses. Skip the missed dose, then go on as before.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, cimetidine can cause side effects, although not everybody gets them.

If you have an allergic reaction to this medicine, STOP taking the medicine and see a doctor immediately.

An allergic reaction may include:

- any kind of skin rash or "hives", flaking skin, boils or sore lips, swelling (of the face, eyelids, lips, mouth or tongue), fever, swollen blood vessels
- sudden wheezing, fluttering or tightness of the chest, chest pain, feeling faint especially when standing up or collapse.

Seek immediate medical attention if you have any of the following symptoms:

- unusual bleeding or bruising; or fever, sore throat, mouth ulcers, repeated infections or infections that will not go away. This may be due to changes in your blood
- red spots on the skin which may be painful to touch, joint pain, swollen lymph glands
- yellowing of your skin or eyes, pale faeces and dark urine, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness. This may be due to liver changes
- confusion, hallucinations, depression
- in men: enlarged breasts, trouble getting or keeping an erection
- unexpected secretion of breast milk in men or women
- pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever. This may be due to inflammation of the pancreas

- unusually slow or fast heartbeat, irregular heartbeat and fainting
- fever, rash, nausea, aches and pains, change in colour of urine, passing more or less urine than usual or passing urine at night. These problems may indicate kidney changes
- aching or weak muscles, or aching joints.

Other possible side-effects:

Common (affects 1 to 10 users in 100)

- diarrhoea
- dizziness
- tiredness
- mild skin rash
- headache.

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

- hair loss.

Side effects with Cimetidine Oral Solution are usually mild and do not last long.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cimetidine Oral Solution

- Keep out of the sight and reach of children
- Do not store above 25°C and keep out of direct sunlight
- Do not use 1 month from the date you first open it
- Do not use after the expiry date which is stated on the label and carton (exp: month, year)
- The expiry date refers to the last day of that month
- Do not use Cimetidine Oral Solution if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cimetidine Oral Solution contains

- The active substance is cimetidine
- The other ingredients are methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol (E1520), liquid maltitol (E965) (containing sorbitol (E420)), hydrochloric acid, disodium hydrogen phosphate (E339), saccharin sodium, ammonium glycyrrhizinate, peach and peppermint flavour (containing propylene glycol), sunset yellow (E110) and purified water.

What Cimetidine Oral Solution looks like and contents of the pack

A clear yellow/orange liquid with an odour of peppermint and peach.

It comes in a brown glass bottle holding 300ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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