

Patient Information Leaflet
Recim-200 Tablets
Cimetidine BP 200 mg

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 further questions, ask your doctor or your 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

- a. What Recim-200 Tablets is and what it is used for
- b. Before you take Recim-200 Tablets
- c. How to take Recim-200 Tablets
- d. Possible side effects
- e. How to store Recim-200 Tablets
- f. Further information

a. What Recim-200 Tablets is and what it is used for

Recim-200 Tablets contains the active ingredient called Cimetidine. Cimetidine belongs to a group of medicines called Histamine H₂ - receptor antagonists and is used as anti-ulcer drug. It works by reducing the amount of acid in your stomach.

The tablets are used to treat and relieve the following conditions:

- Ulcers in the stomach (gastric ulcer) and in upper part of the intestine (duodenum ulcer)
- Recurrent or stomach ulcers (ulcers that keep coming back or which have occurred following stomach surgery).
- 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)
- Acid from the stomach escaping into the food pipe causing pain, inflammation and heartburn (oesophageal reflux).
- Persistent heartburn and stomach pain.
- Upper abdominal pain particularly after meals
- Prevent of internal bleeding from ulcers caused by stress in seriously ill patients.
- For patients at risk of acid inhalation before general anaesthesia particularly pregnant women during labour (Mendelson's syndrome).
- Improve absorption of food and reduce fluid loss in short bowel syndrome.

- Reduce the breakdown of pancreatic enzyme supplements in patients with pancreatic problems.
- Excess acid in the stomach caused by a tumour in the pancreas (Zollinger-Ellison syndrome).

b. Before you take Recim-200 Tablets

Do not take Recim-200 Tablets:

- if you are allergic to cimetidine, or any of the other ingredients listed of this medicine (listed in section f).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Recim-200 Tablets

- if you suffer from kidney problems or from gastric cancer.
- if you are suffering liver problems.
- if you have a history of peptic ulcer, particularly if you are taking a non-steroidal anti-inflammatory drug (NSAIDs) e.g. aspirin, ibuprofen, naproxen, diclofenac.
- if you are middle aged or over, with new or recently changed indigestion symptoms (e.g. Stomach pain or discomfort, heartburn), other causes of your symptoms such as stomach cancer, should be excluded.

Other medicines and Recim-200 Tablets

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

- Anticoagulants (thin the blood) (e.g. warfarin)
- Anticonvulsants (prevent fits) (e.g. phenytoin, diazepam)
- Bronchodilators (for breathing difficulties) (e.g. theophylline)
- Immunosuppressant's (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)
- Heart medicines (e.g. diltiazem, nifedipine, lidocaine, propranolol, metoprolol, procainamide or quinidine)
- Antidiabetics (lowers glucose levels in the blood) (e.g. metformin or glipizide)
- Anti-cancer drugs (treatment of cancer or tumor) (e.g. carmustine, fluorouracil, epirubicin, or therapies such as radiation)
- Strong pain killers (e.g. morphine).
- Tricyclic antidepressants (used to treat depression) (e.g. amitriptyline).
- Antiretroviral drug (used to treat HIV/AIDs) (e.g. atazanavir)
- Tacrolimus for eczema

Pregnancy and breast-feeding

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.

Do not take Recim-200 Tablets during breast feeding because cimetidine is excreted in breast milk and can be harmful for your child.

The use of Recim-200 Tablets during pregnancy and breast-feeding should be avoided unless considered essential by your doctor.

Driving and using machines

Recim-200 Tablets will not affect your ability to drive or to use machinery.

Recim-200 Tablets contain Sodium.

This medicine contains less than 1mmol sodium (23mg) per dosage unit, that is to say essentially sodium-free.

c. How to take Recim-200 Tablets

Always take Recim-200 Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For oral administration only.

The maximum daily dose of 2.4g (i.e. 2,400mg) should not be exceeded. Dosage should be reduced in patients with kidney problems. Treatment should be given for at least 4 weeks (duodenal ulceration), 6 weeks (benign gastric ulceration) and 8 weeks (ulcer associated with continued non-steroidal anti-inflammatory drug). If the ulcer has not healed, your doctor may recommend another course.

Adults

The recommended dose is 400 mg twice a day with breakfast and at bedtime or one 200mg tablet three times a day with meals followed by 400mg at bedtime. If inadequate 400mg four times a day with meals and at bedtime. Your doctor will decide the right dose for you, depending on your condition.

Elderly

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

Children over 1 year of age

The recommended dose for children over one year old is 25 to 30 mg/kg body weight each day in divided doses. "Your doctor will decide the right dose, depending on your child's weight."

If you take more Recim-200 Tablets than you should

If you take more than the prescribed dose, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

If you forget to take Recim-200 Tablets

Do not take a double dose to make up for forgotten dose. Take your normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take the missed dose and continue as usual.

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

d. Possible side effects

Like all medicines, Recim-200 Tablets can cause side effects, although not everybody gets them. You must stop taking the tablets and tell your doctor immediately, if you notice any of the following side effects:

- Rash
- Itching or hives on the skin
- Swelling of the face, or other parts of the body
- Shortness of breath, wheezing or trouble breathing.

Other side effects which have been observed during treatment with Recim-200 Tablets are listed below by how likely they are:

Common (may affect up to 1 in 10 people)

- Headache, dizziness
- Diarrhoea
- Muscular pain
- Tiredness

Uncommon (may affect up to 1 in 100 people)

- Decrease in white blood cells
- Depression, confusional states, hallucinations
- Faster heart beat
- Abdominal pain, yellowing of the skin/eyes and dark coloured urine.
- Kidney problems
- Breasts enlargements and trouble getting or keeping an erection (impotence).

Rare (may affect up to 1 in 1,000 people)

- Decrease in blood cell types (anaemia)
- Irregular heartbeat
- Liver inflammation
- Kidney swelling

Very Rare (may affect up to 1 in 10,000 people)

- Decrease in blood cells, Lowered white blood cell count
- Slow Heart beat (Bradycardia)
- Inflammation of the pancreas
- Hair loss
- Joint pain
- Lactation
- Fever

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.

e. How to store Recim-200 Tablets

Do not store above 30°C.

Protect from light.

Keep out of reach of children.

Do not use Recim-200 Tablets after the expiry date which is started on the label or carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer use. These measures will help to protect the environment.

f. Further information

What Recim-200 Tablets contains

Each uncoated tablet contains Cimetidine BP 200 mg

The other ingredients are Maize starch, Lactose anhydrous, Microcrystalline cellulose, Povidone (PVPK 30), Sodium methyl paraben, Sodium propyl paraben, Brilliant blue supra, Tartrazine supra, Colloidal silicon dioxide, Sodium starch glycollate, Magnesium stearate.

What Recim-200 Tablets looks like and contents of the pack

Round biconvex shaped light green coloured tablets, plain on both sides.

Aluminium/PVC blister strip of 10 tablets and 10 of such blister strips are packed in a unit box with pack insert.

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A milestone to Golden Health