175 mm

420 mm

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Cimetidine 200 mg, 400 mg, 800 mg

Tablets

Phama-code area

Read all of this leaflet carefully before you start using 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Cimetidine is and what it is used for

Cimetidine belongs to a group of medicines called H_2 receptor antagonists, which reduce the amount of acid in your stomach.
Cimetidine is used to treat the following:
- Ulcers in the stomach (gastric) or the upper part of the small intestine (duodenum), including those which may be caused by Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
- Reflux and other conditions caused by acid from the stomach escaping into the gullet (oesophagus)
- Persistent symptoms such as indigestion, heartburn, stomach pain (with or without ulcers)
- Excess acid in the stomach caused by tumours in the pancreas or the upper part of the small intestine (duodenum) (Zollinger-Ellison syndrome)
- To prevent stomach ulcers in seriously ill patients
- To prevent damage to the lungs caused by breathing in stomach acid (acid aspiration/Mendelson's Syndrome) and before anaesthetic if you are at risk, particularly during labour
- To improve absorption and reduce fluid loss in short bowel syndrome
- To reduce the breakdown of pancreatic enzyme supplements

2. What you need to know before you take Cimetidine

Do not take if:
- You are allergic to Cimetidine, other H_2 receptor antagonists or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor before taking Cimetidine:
- If you suffer from kidney problems, as the dose of this medicine may need to be reduced
- If you need to take this medicine for a long time as you should see your doctor regularly
- Before starting treatment with Cimetidine, the possibility of gastric cancer should be excluded because Cimetidine can relieve the symptoms. This particularly applies if you are middle aged or older and have new or recently changed symptoms of indigestion or heartburn
- If you have a history of stomach ulcers, particularly if you are older and also taking Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), medicines used to treat certain rheumatic disorders (see "Other medicines and Cimetidine" section)
- If you are taking the following medicines (see "Other medicines and Cimetidine" section):
  - o Medicines used to thin the blood (anticoagulants)
  - o Phenytoin, a medicine used to treat and prevent fits (seizures)
  - o Theophylline, a medicine used to treat breathing disorders

Other medicines and Cimetidine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Medicines which **may interact with or be affected by** Cimetidine:
- Medicines used to thin the blood such as warfarin (anticoagulants), as your dose may need to be reduced
- Phenytoin, a medicine used to treat and prevent fits (seizures) as your dose may need to be reduced
- Theophylline, a medicine used to treat breathing disorders
- Intravenous lidocaine (anaesthetic)
- Tricyclic antidepressants, medicines used to treat depression such as amitriptyline
- Medicines for irregular heartbeat, such as lidocaine (antiarrhythmics)
- Selective Serotonin Reuptake Inhibitors (SSRIs), medicines used to treat depression such as citalopram and sertraline
- Calcium channel blockers, medicines used to treat various conditions of the heart and blood vessels such as nifedipine and diltiazem
- Medicines used to treat diabetes such as glipizide, metformin (oral sulfonylureas)
- Metoprolol, used to treat high blood pressure, chest pain, abnormal rhythms of the heart (beta blocker)
- Procainamide, a medicine used to treat irregular heartbeats
- Ciclosporin, tacrolimus, medicines used to reduce the body's immunity when receiving organ transplant (immunosuppressants)
- Atazanavir, a medicine used to treat HIV infection
- Medicines used to treat fungal infections such as ketoconazole, itraconazole or posaconazole (azole antifungals)
- Medicines used during chemotherapy treatment such as carmustine, fluorouracil, epirubicin
- Radiation therapy
- Strong pain relieving medicines such as morphine (narcotic analgesics)

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 for advice before taking this medicine.

Pregnancy
The use of Cimetidine should be avoided during pregnancy unless essential.

Breast-feeding
If you are breast-feeding, the use of Cimetidine should be avoided unless essential as Cimetidine is passed into breast milk.

Cimetidine contains propylene glycol (E1520)
May cause alcohol-like symptoms.

Cimetidine 800 mg contains sodium
The 800 mg medicine contains 40 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Cimetidine

Always take Cimetidine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- These tablets are to be taken orally
- The score line is not intended for breaking the tablet
- The total daily dose should not normally exceed **2.4 g**
- Your dose should be reduced if you suffer from impaired kidney function
- As Cimetidine may not give immediate relief of symptoms, antacids may be taken until symptoms disappear

Adults
Ulcers:
- The usual recommended dose is a single dose of 800 mg at bedtime or 400 mg twice a day with breakfast and at bedtime
- Other effective doses are 200 mg three times a day with meals and 400 mg at bedtime (1.0 g per day) or, if inadequate, 400 mg four times a day (1.6 g per day) also with meals and at bedtime
- Treatment is usually given initially for at least 4 weeks. Your doctor may extend the treatment if the ulcer(s) have not healed by then
- Treatment may be continued for longer periods and the dose may be reduced as appropriate to 400 mg at bedtime or 400 mg in the morning and at bedtime
- If you have a benign peptic ulcer and have responded to the initial course of treatment, a relapse may be prevented by continued treatment, usually with 400 mg at bedtime. 400 mg in the morning and at bedtime has also been used

Oesophageal Reflux Disease:
The usual dose is 400 mg four times a day, with meals and at bedtime, for 4 to 8 weeks.

Zollinger-Ellison Syndrome:
The dose may be increased to 400 mg four times a day, or occasionally, more.

To prevent ulcers from bleeding (seriously ill patients):
Doses of 200-400 mg can be given **orally** every 4-6 hours.

Acid Respiration Syndrome:
- An oral dose of 400 mg may be given 1.5-2 hours before the induction of a general anaesthetic or the start of labour
- A dose of 400 mg may be repeated (intravenously if appropriate) at 4-hourly intervals as required up to the usual daily maximum of 2.4 g
- Cimetidine syrup should **not** be used
- The usual precautions to avoid acid aspiration should be taken

Short Bowel Syndrome:
The usual dosage range can be used according to your individual response.

To reduce degradation of pancreatic enzyme supplements:
800-1600 mg a day may be given (according to response) in four divided doses, 1-1.5 hours before meals.

Older people
The normal adult dose may be given, unless you suffer from impaired kidney function.

Use in children
- In children **more than** one year old, a dose of 25-30 mg/kg bodyweight per day may be given in divided doses. This may be administered either orally or intravenously
- In children **under** one year old, a dose of 20 mg/kg body weight per day, may be given in divided doses

If you take more Cimetidine than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take Cimetidine
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Cimetidine
It is important that you keep taking Cimetidine for as long as your doctor has told you to.

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.

Seek medical advice immediately if you develop the following symptoms:
- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness
- Difficulty breathing or dizziness (anaphylaxis). This usually clears on stopping treatment with Cimetidine
- Inflammation of the pancreas (pancreatitis). This clears on stopping treatment with Cimetidine
- Skin rash caused by the inflammation of blood vessels resulting from a sensitivity (allergy) to a medicine (hypersensitivity vasculitis). This usually clears on stopping treatment with Cimetidine

Common side effects (may affect up to 1 in 10 people)
- Headaches
- Dizziness
- Diarrhoea
- Skin rashes
- Muscle pain (myalgia)
- Tiredness

Uncommon side effects (may affect up to 1 in 100 people)
- Reduction in white blood cells (leukopenia)
- Depression
- Confusion. This is reversible within a few days of stopping treatment with Cimetidine
- Seeing or hearing things that are not real (hallucinations)
- Faster heartbeat (tachycardia)
- Inflammation of the liver (hepatitis). This clears on stopping treatment with Cimetidine
- Increase in plasma creatinine (detected through kidney function (blood) tests). The increases do not progress with continued treatment with Cimetidine and disappear on stopping treatment
- Excessive development of the male breast (gynaecomastia). This is usually reversible upon stopping treatment with Cimetidine
- Inability to maintain an erection (impotence). This is reversible

Rare side effects (may affect up to 1 in 1000 people)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia)
- Slower heartbeat (bradycardia)
- Increase in serum transaminase levels (detected through liver function (blood) tests). The increase in levels is cleared on stopping treatment with Cimetidine
- Inflammation of the kidney (interstitial nephritis). This clears on stopping treatment with Cimetidine

Very rare side effects (may affect up to 1 in 10,000 people)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- More prone to infections due to a severe reduction in number of white blood cells (agranulocytosis)
- The heart beats irregularly or much more slowly than normal (heart block)
- Hair loss (alopecia) (reversible)
- Pain or swelling in the joints (arthralgia)
- Milky secretion from the breasts not due to breast-feeding (galactorrhoea)
- Fever. This clears on stopping treatment with Cimetidine

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 Yellow Card Scheme at 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

- 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 carton/blister/container after EXP. The expiry date refers to the last day of that month
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment

6. Contents of the pack and other information

What Cimetidine contains:
Each film-coated tablet contains 200 mg, 400 mg or 800 mg of Cimetidine.

The other ingredients are: gelatin, potato starch, talc, magnesium stearate, hypromellose 5 cps, triacetin, macrogol 400, dimeticone 350, titanium dioxide (E171), propylene glycol (E1520), iron oxide (E172) and chlorophyll C-100,000-WS-P (E141).
200 mg & 400 mg also contains microcrystalline cellulose.
800 mg also contains sodium starch glycollate (Type A).

What Cimetidine looks like and the contents of the pack:
- Cimetidine 200 mg are pale green, round, convex, film-coated tablets with an approximate diameter of 9.5 mm coded "CIM/200" on one side with a score line on the other
- Cimetidine 400 mg are pale green, elliptic, convex, film-coated tablets with an approximate size of 8 mm x 16 mm, coded "CIM/400" on one side with a score line on the other
- Cimetidine 800 mg are pale green, oval, convex, film-coated tablets with an approximate size of 9.6 mm x 19 mm coded "CIM/800" on one side with a score line on the other

Cimetidine is available in:
- Cimetidine 200 mg Tablets are available in packs of 28, 30, 50, 56, 60, 112 or 120 tablets
- Cimetidine 400 mg Tablets are available in packs of 28, 30, 50, 56, 60 or 120 tablets
- Cimetidine 800 mg Tablets are available in packs of 28, 30, 50, 60 or 120 tablets

Not all pack sizes or pack types may be marketed.

Product Licence Numbers:
- 200 mg - PL 11311/0172
- 400 mg - PL 11311/0173
- 800 mg - PL 11311/0174

Marketing Authorisation Holder
Tillomed Laboratories Limited
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