



PACKAGE LEAFLET: INFORMATION FOR THE USER

## **CIMETIDINE 200 mg, 400 mg & 800 mg TABLETS (Cimetidine)**

**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 only. Do not pass it on to others. It may harm them, even if their symptoms 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.

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### **1. WHAT CIMETIDINE TABLETS ARE AND WHAT THEY ARE USED FOR**

The name of your medicine is Cimetidine Tablets. It contains the active ingredient called Cimetidine. Cimetidine belongs to a group of medicines called Histamine H<sub>2</sub> - 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).

### **2. BEFORE YOU TAKE CIMETIDINE TABLETS**

**Do not take Cimetidine Tablets:**

- if you are allergic to cimetidine, or any of the other ingredients listed of this medicine (listed in section 6).

### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking Cimetidine 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 Cimetidine 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 Cimetidine Tablets during breast feeding because cimetidine is excreted in breast milk and can be harmful for your child.

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

#### **Driving and using machines**

Cimetidine Tablets will not affect your ability to drive or to use machinery.

#### **Cimetidine Tablets contain Sodium.**

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

### **3. HOW TO TAKE CIMETIDINE TABLETS**

**Always take Cimetidine 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 Cimetidine 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 Cimetidine 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.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Cimetidine 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 Cimetidine 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. You can also report side effects directly via the Yellow Card Scheme at: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. HOW TO STORE CIMETIDINE TABLETS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use Cimetidine 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.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

##### What Cimetidine Tablets contain?

Each **200 mg Tablet** contains 200 mg of the active ingredient cimetidine.

The other ingredients are Starch, Povidone, Magnesium Stearate, Sodium Starch Glycollate, Purified Water, Opadry Oy-8839 (E104, E132, E171, E172).

Each **400 mg Tablet** contains 400 mg of the active ingredient cimetidine. The other ingredients are Starch, Povidone, Magnesium Stearate, Sodium Starch Glycollate, Purified Water, Opadry Oy-8839 (E104, E132, E171, E172).

Each **800 mg Tablet** contains 800 mg of the active ingredient cimetidine.

The other ingredients are Starch, Povidone, Magnesium Stearate, Sodium Starch Glycollate, Purified Water, Opadry Oy-8839 (E104, E132, E171, E172).

##### What Cimetidine Tablets look like and contents of the pack

**Cimetidine 200 mg Tablets** are green round film coated tablets coded CIM on one side and 200 on reverse. Pack sizes: 50, 100, 250, 500, 120, 5000, 84 and 60 tablets. Not all pack sizes may be marketed.

**Cimetidine 400 mg Tablets** are green capsule shaped film coated tablets coded CIM on one side and 400 on reverse. Pack sizes: 50, 56, 60, 100, 250, 500, 2500 and 5000 tablets. Not all pack sizes may be marketed.

**Cimetidine 800 mg Tablets** are green elliptical film coated tablets coded CIM on one side and 800 on reverse. Pack sizes: 28, 30, 50, 100, 250, 500 tablets. Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

###### MEDREICH PLC

Warwick House, Plane Tree Crescent,

Feltham TW13 7HF, UK

E-mail : [info@medreich.co.uk](mailto:info@medreich.co.uk)

**To listen to or request a copy of this leaflet in Braille, large print or audio please call,**

**02088311580 (UK only)**

**Please be ready to give the following information:**

Product name	Reference number
<b>Cimetidine 200 mg Tablets</b>	<b>PL 21880/0088</b>
<b>Cimetidine 400 mg Tablets</b>	<b>PL 21880/0089</b>
<b>Cimetidine 800 mg Tablets</b>	<b>PL 21880/0090</b>

This leaflet was last revised in 08/2018

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<b>MEDREICH LIMITED</b>				<b>Title: Art Work Approval Form</b>			
Product	<b>Cimetidine Tablets - S/L - Eng - PIL</b>			Specification:	<b>Printed on 56 - 60 GSM Maplitho paper.</b>		
Customer	<b>MEDREICH PLC, UK</b>						
Reason for Issue	<b>AWR No.:</b> (old code: 1214286-V1) New word doc file received from customer.			Colours:	<b>Single - Black</b>		
Related FG Codes	<b>1302601, 1303666, 1303671</b>	Pharmacode No.	<b>2964</b>	Dimensions:	<b>220 x 190 mm (Open Size),</b>		
Item Code	<b>121XXXX-V1 (WOA)</b>	Layout No.:	<b>NA</b>	No. of Folds (only for PIL)	<b>XX</b>	Artwork made to	<b>100%</b>
Verified By			Approved By				
<b>PDC:</b>	<b>PDC:</b>	<b>Regulatory:</b>	<b>QC:</b>	<b>CQA:</b>			