

## Package Leaflet: Information for the user

### CIMELDINE 400mg Film-coated Tablets

#### Cimetidine

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

#### What in in this leaflet

1. What Cimeldine is and what it is used for
2. What you need to know before you take Cimeldine
3. How to take Cimeldine
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#### 1. What Cimeldine is and what it is used for

The name of your medicine is Cimeldine, it contains the active ingredient cimetidine, which reduces the amount of acid being produced by your stomach (gastric acid). By reducing the amount of acid produced, this can help ulcers to heal and give relief where gastric acid is causing discomfort.

This medicine is used for the treatment of stomach/intestinal ulcers, Zollinger-Ellison Syndrome (excessive secretion of acid by the stomach) and other conditions benefiting from a reduced secretion of gastric acid, ulceration of the oesophagus caused by the reflux of gastric juices and to help prevent the recurrence of stomach/intestinal ulcers.

#### 2. Before you take Cimeldine

##### Do not take Cimeldine

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Cimeldine

- if you have an illness that could cause a fall in blood cell count
- if you have a kidney or liver complaint or blood disorder
- if you are elderly or are very ill
- if you have or have had a stomach ulcer or duodenal ulcer before. You should discuss this with your doctor particularly if you are taking a non-steroidal anti-inflammatory drug
- if you are middle aged or older, 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
- if you are elderly, have a chronic lung disease, have diabetes or are immunocompromised. You are at greater risk of getting pneumonia (lung infection) while taking Cimeldine tablets.

If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Cimeldine tablets, this is especially important if you are likely to have an **anaesthetic** or an **operation**.

Some patients may be at higher risk of chest infections when given Cimeldine Tablets. If you are very elderly or have a pre-existing lung complaint talk to the doctor or pharmacist before you are given

Cimeldine. Also, if you develop a cough or a chest-infection while on Cimeldine, you should tell the doctor.

### **Other medicines and Cimeldine**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Cimeldine may increase the effects of other drugs. It is especially important for your doctor to know if you are already being treated with any of the following medicines:

- Medicines used to thin your blood (coumarin anticoagulants) e.g. warfarin. If you are already taking these and you take cimeldine as well your blood will be checked more often
- Medicines to prevent fits (anticonvulsants e.g. phenytoin)
- Medicines to help your breathing (e.g. theophylline)
- Medicines that cause a fall in blood cell count
- Tricyclic antidepressants, e.g. amitriptyline
- Heart medicines, e.g. diltiazem, lidocaine, nifedipine, metoprolol, procainamide
- Medicines for diabetes, e.g. glipizide, metformin
- Cyclosporin, which can be used to prevent organ rejection or rheumatism
- Tacrolimus, for eczema
- Atazanavir for AIDS/HIV
- Antifungal medicines, e.g. ketoconazole, itraconazole, or posaconazole
- Medicines or treatments for tumours or cancer, e.g. carmustine, fluorouracil, epirubicin or radiation therapy
- Strong pain killers, e.g. morphine

### **Cimeldine with food and drink**

Cimeldine tablets can be taken with or without food

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Cimeldine tablets are not likely to affect you being able to drive or use any tools or machines.

### **Cimeldine tablets contain sodium**

The tablets contain less than 1 mmol sodium (23 mg) per 400 mg, *i.e.*, essentially 'sodium free'.

## **3. How to take Cimeldine**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

### **Stomach/intestinal ulcer**

800 mg daily, taken as a single dose at bedtime **or** 400 mg at breakfast and at bedtime.

### **Prevention of relapse in patients with benign peptic ulceration**

400 mg once daily at bedtime. Your doctor may prescribe a dose of 400 mg in the morning and 400 mg at bedtime.

### **Zollinger-Ellison Syndrome**

400 mg four times daily (total 1600 mg daily).

### **Ulceration of the oesophagus from the reflux of gastric juices**

400 mg with each of the three meals and 400 mg at bedtime (total 1600 mg daily).

**Prevention of bleeding from stress ulceration**

200 to 400 mg taken every 4 – 6 hours. Your doctor may prescribe a total daily dose of 2,400 mg (2.4 g).

**Prevention of acid aspiration (Mendelson's syndrome)**

Your doctor may prescribe a single dose of 400 mg Cimeldine, taken 90 – 120 min before surgery, or at the start of labour if you are pregnant. Your doctor may repeat this dose (400 mg) every 4 hours, up to a maximum dose of 2,400 mg (2.4 g) per day.

**Pancreatic insufficiency (to protect pancreatic enzyme supplements)**

800 to 1,600 mg daily in four divided doses, taken one to one and a half hours before meals.

Your doctor may prescribe a different dosage to those described above. The maximum TOTAL DAILY dosage of Cimeldine is 2,400 mg (2.4 g).

Treatment is usually for a period of at least 4 weeks, though it may be longer (at least 6 or 8 weeks) in some conditions.

Use in children and adolescents

If Cimeldine is prescribed for a child make sure that the tablets are taken as stated on the label.

Cimeldine is not recommended for children younger than 2 years of age.

You should swallow the tablets with a drink of water.

You should continue taking your tablets until the prescribed course has been completed. If you stop your treatment too soon your symptoms may return.

Patients taking this medicine on a long-term basis should be under regular supervision by their doctor.

**If you take more Cimeldine than you should**

If you have taken more Cimeldine than you should, you should contact your doctor or nearest hospital casualty department or poison centre immediately.

**If you forget to take Cimeldine**

Do not take a double dose to make up for a forgotten tablet, simply continue to take the tablets 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, this medicine can cause side effects, although not everybody gets them. The following side effects may occur with this medicine:

**Allergic reactions:**

If you have an allergic reaction, **STOP** taking this medicine and see a doctor **straight away**. The signs may include skin rashes, itching, swelling, fainting or shortness of breath.

**Common (may affect up to 1 in 10 people)**

- Headache
- Dizziness
- Diarrhoea
- Skin rashes
- Tiredness
- Muscle pain (myalgia)

**Uncommon (may affect up to 1 in 100 people)**

- A reduction in the number of white blood cells in the blood leading to an increased risk of infection (leucopenia)
- Depression
- Hallucination
- Confusion (usually in the elderly or ill patients)
- Faster heart beat (tachycardia)
- Hepatitis which may cause one of the following: nausea (feeling sick), vomiting (being sick), loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine
- Breast swelling in men (gynaecomastia)
- Being unable to get an erection (impotence)
- Small increases in creatinine (a chemical commonly found in blood). Creatinine can be measured in blood as an indicator of kidney function.

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

- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Aplastic anaemia in which the red and white blood cells and platelets are all reduced in number (symptoms might include tiredness, being short of breath, looking pale, frequent infections, bruising more easily or nose bleeds)
- A slowness of the heartbeat, usually under 60 beats per minute in adults (sinus bradycardia)
- Increase in level of liver enzymes (serum transaminases) which may be a sign of liver damage
- Inflammation of the kidney (nephritis). Symptoms may include changes in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash.

**Very rare (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)
- Severe reduction in number of white blood cells which makes infections more likely (agranulocytosis)
- Serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis)
- Heart condition causing a very slow heart rate (heart block)
- Reversible hair loss (alopecia)
- Inflammation of blood vessels, often with skin rash (vasculitis)
- Joint pain (arthralgia)
- Secretion of milk after breast feeding has been stopped (galactorrhoea)
- Fever
- Inflammation of the pancreas, which causes severe pain in the abdomen and back

**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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Cimeldine**

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 blister and carton after Exp. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from moisture. Keep blister in outer carton.

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

## **6. Contents of the pack and other information**

### **What Cimeldine contains**

The active substance is cimetidine. Each tablet contains 400 mg cimetidine.

The other ingredients are:

#### *Tablet core:*

Sodium laurilsulfate, microcrystalline cellulose, colloidal anhydrous silica, sodium starch glycollate Type A, magnesium stearate and povidone.

#### *Film-coat:*

Hypromellose, titanium dioxide (E171), macrogol, quinoline yellow aluminium lake (E104), iron oxide yellow (E172), FD & C blue #2/Indigo carmine aluminium lake (E132).

### **What Cimeldine looks like and contents of the pack**

Pale green, oblong, biconvex, film-coated tablets marked with the Clonmel logo on one side and the code 275 on the reverse.

Pack size: 60 and 100 tablets

Not all packs sizes may be marketed.

### **Marketing Authorisation Holder:**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

### **Manufacturer:**

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary  
STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

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