Cimetidine 200 mg Film-Coated Tablets
Cimetidine 400 mg Film-Coated Tablets
Cimetidine 800 mg Film-Coated Tablets

PL 17907/0357-9

UKPAR

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Cimetidine 200 mg, 400 mg & 800 mg Film-Coated Tablets

PL 17907/0357-9

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Bristol Laboratories Limited Marketing Authorisations (licences) for the medicinal products Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets (PL 17907/0357-9) on 16th September 2011. These are prescription-only medicines (POM).

The active ingredient, cimetidine, belongs to a group of medicines called H2-antagonists. It works by preventing your stomach from producing too much acid. The tablets are used to:

- Treat and prevent ulcers in your stomach and the first part of your small intestine;
- Prevent acid coming up your throat;
- Prevent your stomach from producing too much acid which could cause pain and discomfort, such as heartburn, indigestion or dyspepsia;
- Prevent acid coming up from the stomach during childbirth;
- Prevent ulcers caused by stress;
- Prevent bleeding from ulcers;
- Prior to general anaesthetic in patients at risk from stomach acid being sucked into the air passages (Mendelson’s Syndrome), particularly pregnant patients during labour;
- Reduce malabsorption and fluid loss in short bowel syndrome.

These applications are considered to be identical to the previously granted licences for ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90), authorised to Medreich plc on 18th January 2010. The proposed and reference products are identical.

No new or unexpected safety concerns arose from these simple applications. It was judged that the benefits of Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets outweigh the risk; hence Marketing Authorisations have been granted.
Cimetidine 200 mg, 400 mg & 800 mg Film-Coated Tablets

PL 17907/0357-9

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Bristol Laboratories Limited Marketing Authorisations for the medicinal products Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets (PL 17907/0357-9) on 16th September 2011. The products are prescription-only medicines.

These are simple, abridged, ‘informed consent’ applications, submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross-referencing the Marketing Authorisations for ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90), licensed to Medreich plc. The cross-referenced products were originally authorised to Eastern Pharmaceuticals Limited (PL 11382/0012-14) in May 1993 and underwent a series of Change of Ownership (CoA) procedures, with the final CoAs to the current Medreich plc licences on 18th January 2010.

Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets are indicated for the following:

- Benign gastric and duodenal ulceration, stomal ulcer, reflux oesophagitis, Zollinger - Ellison syndromes, other conditions where gastric acid reduction is beneficial.
- Prophylaxis of gastro-intestinal haemorrhage from stress ulceration in seriously ill patients.
- Before general anaesthesia in patients thought to be at risk of acid aspiration (Mendelson’s) syndrome, particularly obstetric patients during labour.
- To reduce malabsorption and fluid loss in the short bowel syndrome.

Cimetidine is an H2 blocker with reversible competitive antagonism of the actions of histamine. Cimetidine inhibits gastric acid secretion elicited by histamine or other H2 antagonists, it also inhibits the gastric secretion, reduces the volume of juice secreted and its hydrogen ion concentration.

The MHRA considers that the pharmacovigilance system described by the Marketing Authorisation Holder (MAH) fulfils the requirements and provides adequate evidence that the MAH has the services of a Qualified Person (QP) responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The MAH has provided adequate justification for not submitting a Risk Management Plan (RMP). As the applications are for products that are identical to already authorised reference products, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference products have been in use for many years and the safety profile of the active is well-established.

The MAH has provided adequate justification for not submitting an Environmental Risk Assessment (ERA). It is not considered that these medicinal products represent any risk to the environment. There is no reason to conclude that marketing of these
products will change the overall use pattern of the existing market. The availability of these medicinal products, which are identical to the cited reference products, will not lead to any increase in environmental exposure concentrations of the active ingredient.

No new data were submitted nor was it necessary for these simple applications, as the data are identical to those of the previously granted cross-reference products. As the cross-reference products were first granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for them.
PHARMACEUTICAL ASSESSMENT

1. INTRODUCTION

These are simple abridged applications, submitted under Article 10(c) of Directive 2001/83/EC (as amended) for Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets. The proposed MAH is Bristol Laboratories Limited.

The reference products are ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90), authorised to Medreich plc on 18th January 2010. The proposed and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved names of the products are Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets. The products have been named in line with current requirements and the product names are acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each film-coated tablet contains 200 mg, 400 mg or 800 mg of the active ingredient cimetidine. The tablets are licensed for marketing in polyvinylidene chloride (PVdC) coated polyvinylchloride (PVC) - aluminium foil blister strips, which are packed with the Patient Information Leaflet (PIL) into cardboard outer cartons, in pack sizes of 50, 60, 84, 100, 120, 250, 500, and 5000 film-coated tablets (200 mg strength), 50, 56, 60, 100, 250, 500, 2500 and 5000 film-coated tablets (400 mg strength), and 28, 30, 50, 100, 250 and 500 film-coated tablets (800 mg strength). The MAH has stated that not all pack sizes may be marketed. The container closure systems and pack sizes are identical to those for the reference products.

The approved shelf-life (3 years) and storage conditions (‘Store below 25°C’) are identical to the details registered for the reference products.

2.3 Legal status

POM - The products are available subject to a medical prescription.

2.4 Marketing Authorisation Holder / Contact Persons/Company

The proposed Marketing Authorisation Holder is ‘Bristol Laboratories Ltd, Unit 3, Canalside, Northbridge Road, Berkhamsted, Herts HP4 1EG’.
The Qualified Person (QP) responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch sizes are stated.

2.8 Finished product / shelf-life specification
The proposed finished product specifications are in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specifications are consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
The magnesium stearate has been confirmed as being of vegetable origin. There are no materials of human or animal origin contained in or used in the manufacturing process for the proposed products. None of the excipients are sourced from genetically modified organisms.

3. EXPERT REPORT
A satisfactory quality overall summary has been prepared by an appropriately qualified expert. The CV of the expert was provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The 200 mg strength tablets are pale green, circular, biconvex, film-coated tablets, plain on one side and embossed “CIM 200” on the reverse. The 400 mg strength tablets are pale green, oblong, film-coated tablets, plain on one side and embossed “CIM 400” on the reverse. The 800 mg strength tablets are pale green, oval, film-coated tablets, plain on one side and embossed “CIM 800” on the reverse. The appearance of the products is similar to that of the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The approved SmPCs are consistent with the details registered for the cross-reference products.
6. PATIENT INFORMATION LEAFLET (PIL) / LABELLING

PIL
The approved PIL is satisfactory and in line with the approved SmPCs. It has been prepared according to the Quality Review of Documents (QRD) template and is consistent with the details registered for the cross-reference products.

PIL user-testing has been accepted based on bridging to the successful user-testing of the PIL for the reference products, ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90). The text, content and layout of the proposed PIL are essentially identical to the approved PIL for the reference products. The bridging is accepted.

Labelling
Mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. In line with current legislation the applicant has included the name of the products in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

The MAH has stated that not all licensed pack sizes may be marketed. They have committed to submitting mock-ups for currently unmarketed pack sizes to the MHRA for approval before those packs are commercially marketed.

7. CONCLUSIONS
The grounds for these applications are considered adequate. Marketing Authorisations were therefore granted.
NON-CLINICAL ASSESSMENT

These are simple, abridged, ‘informed consent’ applications made under Article 10(c) of EC Directive 2001/83 (as amended).

No new non-clinical data have been supplied with these applications and none are required for applications of this type. A non-clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environmental Risk Assessment (ERA).
CLINICAL ASSESSMENT

These are simple, abridged, ‘informed consent’ applications made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to the Marketing Authorisations for ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90; Medreich plc).

No new clinical data have been supplied with the applications, and none are required for applications of this type. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The data for these applications are consistent with those previously assessed for the cross-reference products and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
These applications are considered identical to the previously granted licences for ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90; Medreich plc).

No new or unexpected safety concerns arise from these applications.

PRODUCT LITERATURE
The approved SmPCs and PIL are satisfactory and consistent with the details registered for the cross-reference products.

PIL user-testing has been accepted based on bridging to the successful user-testing of the PIL for the reference products, ZITA/Cimetidine Tablets 200 mg, 400 mg and 800 mg (PL 21880/0088-90).

The approved labelling artwork complies with statutory requirements. In line with current legislation, the name of the product in Braille appears on the outer packaging and sufficient space has been included for a standard UK pharmacy dispensing label. The MAH has stated that not all licensed pack sizes may be marketed. They have committed to submitting mock-ups for unmarketed pack sizes to the MHRA for approval before those packs are marketed.

BENEFIT-RISK ASSESSMENT
The quality of the products is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s products are identical to the cross-reference products. The benefit: risk ratio is considered to be positive.
Cimetidine 200 mg, 400 mg & 800 mg Film-Coated Tablets

PL 17907/0357-9

**STEPS TAKEN FOR ASSESSMENT**

1. The MHRA received the marketing authorisation applications on 15\textsuperscript{th} December 2010.

2. Following standard checks and communication with the applicant the MHRA considered the applications valid on 25\textsuperscript{th} January 2011.

3. Following assessment of the application the MHRA requested further information relating to the quality dossier on 30\textsuperscript{th} March 2011, 20\textsuperscript{th} June 2011 and 8\textsuperscript{th} August 2011.

4. The applicant responded to the MHRA’s requests, providing further information for the quality sections on 20\textsuperscript{th} May 2011, 15\textsuperscript{th} July 2011 and 22\textsuperscript{nd} August 2011 respectively.

5. The applications were determined on 16\textsuperscript{th} September 2011.
Cimetidine 200 mg, 400 mg & 800 mg Film-Coated Tablets

PL 17907/0357-9

STEPS TAKEN AFTER AUTHORISATION

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Cimetidine 200 mg, 400 mg and 800 mg Film-Coated Tablets (PL 17907/0357-9) is as follows – Differences between the individual SmPCs are highlighted:

1 NAME OF THE MEDICINAL PRODUCT

Cimetidine 200mg Film-Coated Tablets
Cimetidine 400mg Film-Coated Tablets
Cimetidine 800mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 200/400/800 mg cimetidine USP as the active ingredient.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film coated tablets.
(tablet)

200 mg tablets: Pale green, circular, biconvex, film coated tablet plain on one side and embossed “CIM 200” on the reverse.

400 mg tablets: Pale green, oblong, film-coated tablet plain on one side and embossed “CIM 400” on the reverse.

800 mg tablets: Pale green, oval, film-coated tablet plain on one side and embossed “CIM 800” on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Benign gastric and duodenal ulceration, stomal ulcer, reflux oesophagitis, Zollinger - Ellison syndromes, other conditions where gastric acid reduction is beneficial.

The prophylaxis of gastro-intestinal haemorrhage from stress ulceration in seriously ill patients.

Before general anaesthesia in patients thought to be at risk of acid aspiration (Mendelsson’s) syndrome, particularly obstetric patients during labour.

To reduce malabsorption and fluid loss in the short bowel syndrome.

4.2 Posology and method of administration

Adults:

The usual dosage is 400 mg twice a day with breakfast and at bedtime. Duodenal ulceration may be treated with a single daily dose of 800 mg at bedtime. Other effective regimens are 200 mg three times a day with meals and 400 mg at bedtime (1.0 g/day) and, if inadequate, 400mg four times a day (1.6g/day) with meals and at bedtime.

Treatment should be given initially for at least four weeks (six weeks in benign gastric ulcer) even if symptomatic relief has been achieved sooner.

Treatment may be continued for longer periods in patients who may benefit from reduction of gastric secretion and the dosage may be reduced in those who have responded to treatment, for example to 400 mg at bedtime or 400 mg in the morning and at bedtime.

In patients with benign peptic ulcer disease who have responded to the initial course, relapse may be prevented by continued treatment. Usual dosage for maintenance treatment is 400 mg at bedtime but 400 mg in the morning and at bedtime has also been used. In oesophageal reflux disease, 400 mg four times a day with meals and at bedtime for four to eight weeks is recommended.
In patients with very high gastric acid secretion (e.g. Zollinger-Ellison syndrome) it may be necessary to increase the dose to 400 mg four times a day, or in occasional cases further.

Antacids can be made available to all patients until symptoms disappear.

In the prophylaxis of haemorrhage from stress ulceration in seriously ill patients up to a usual maximum of 2.4 g per day can be given in divided doses to maintain intragastric pH above 4.

In patients thought to be at risk of acid aspiration syndrome an oral dose of 400 mg can be given 90 - 120 minutes before induction of general anaesthesia.

Up to this dose may be repeated (parenterally if appropriate) as required if operation is prolonged. In obstetric patients during labour, an initial oral dose of 400 mg at the start of labour followed by 200 mg every two hours to a maximum of 1.6 g has been used. The usual precautions to avoid acid aspiration should be taken.

In the short bowel syndrome, e.g. following substantial resection for Crohn's disease, the usual dosage can be used.

Use in the elderly:
The normal adult dosage should be used unless renal function is markedly impaired.

Use in children over 1 year:
20 to 30 mg/kg daily in divided doses.

Route of administration:
Oral

4.3 Contraindications
No known contraindications.

4.4 Special warnings and precautions for use
Use of cimetidine in treatment for undiagnosed dyspepsia is undesirable because, by ameliorating symptoms and inducing surface healing, it can delay the diagnosis of gastric cancer.

Dosage should be reduced in patients with impaired renal function according to creatinine clearance. The following dosages are suggested:

<table>
<thead>
<tr>
<th>Creatinine clearance of</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 15 mg/minute</td>
<td>200 mg twice a day</td>
</tr>
<tr>
<td>15 to 30 ml/minute</td>
<td>200 mg three times a day</td>
</tr>
<tr>
<td>30 to 50 ml/minute</td>
<td>200 mg four times a day</td>
</tr>
<tr>
<td>over 50 ml/minute</td>
<td>normal dosage</td>
</tr>
</tbody>
</table>

Cimetidine is removed by haemodialysis.

In patients on drug treatment or with illnesses that could cause falls in blood count, the possibility that H2-receptor antagonism could potentiate the effect should be borne in mind.

4.5 Interaction with other medicinal products and other forms of interaction
Care should be exercised when cimetidine is given simultaneously with metoprolol, propranolol and labetalol due to the possibility of increased bioavailability of these betablockers.

The elimination of diazepam (and its main metabolite desmethyldiazepam) and chlordiazepoxide has been shown to be prolonged in normal subjects and it is prudent that patients should be monitored for excessive sedation when these agents and cimetidine are administered concurrently. Augmentation of sedation should also be monitored when cimetidine and chlormethiazole are used in combination.
Caution is necessary when cimetidine is given simultaneously with anticoagulants owing to reduced rate of metabolism of these agents. Careful monitoring of the coagulation status of the patient is advised. Similarly the metabolism of phenytoin, carbamazepine and theophylline (or aminophylline) can be prolonged with concurrent use of cimetidine, and plasma levels of these drugs should be monitored and dosage reduced as necessary.

Renal clearance of drugs such as procainamide is retarded.

4.6 Pregnancy and lactation

Although tests in animals have not revealed any hazards from the administration of cimetidine during pregnancy or lactation, both these and studies in women have shown that it does cross the placental barrier and is excreted in milk. As with most drugs, the use of cimetidine should be avoided during pregnancy and lactation unless essential.

4.7 Effects on ability to drive and use machines

In view of reported dizziness and tiredness when taking cimetidine patients should be warned of these possibilities and that they may affect their ability to drive or operate machinery.

4.8 Undesirable effects

Diarrhoea, dizziness or rash, usually mild and transient, and tiredness have been reported. Gynaecomastia has been reported and is almost always reversible on discontinuing treatment. Biochemical or biopsy evidence of reversible liver damage has been reported occasionally. Reversible confusional states have occurred, usually in elderly or already very ill patients, e.g. those with renal failure. There have been very rare reports of interstitial nephritis, acute pancreatitis, thrombocytopenia, headache, myalgia and arthralgia, all reversible on withdrawal of treatment. Alopecia has been reported but no causal relationship has been established. Reversible impotence has also been very rarely reported but no causal relationship has been established at usual therapeutic doses. Isolated increases of plasma creatinine have been of no clinical significance.

4.9 Overdose

In acute overdosage the induction of vomiting and / or gastric lavage may be employed together with symptomatic and supportive therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cimetidine is an H2 blocker with reversible competitive antagonism of the actions of histamine. Cimetidine inhibits gastric acid secretion elicited by histamine or other H2 antagonists, it also inhibits the gastric secretion, reduces the volume of juice secreted and its hydrogen ion concentration.

5.2 Pharmacokinetic properties

Cimetidine is reported to be rapidly absorbed from the gastro-intestinal tract with an elimination half life of around 2 - 3 hours. Peak plasma concentrations are attained in about 1 - 2 hours and there is a reported large inter subject variation occurring in Cmax and Tmax and AUC’s.

Over two-thirds of a dose is excreted in the urine within 24 hours, following parenteral administration this is mainly as unchanged cimetidine, but following oral administration a portion is metabolised, mainly to the sulphoxide. Cimetidine crosses the placental barrier and excreted in milk. It does not readily cross the blood-brain barrier.

5.3 Preclinical safety data

Not applicable
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch
Povidone
Magnesium Stearate
Sodium Starch Glycollate
Purified Water

Additionally for 200 and 400 mg strength tablets: Opadry Oy-8839 (E104, E132, E171, E172)

Additionally for 800 mg strength tablets: Hydroxypropyl Methyl cellulose, Polyethylene Glycol 400

6.2 Incompatibilities

None known

6.3 Shelf life

- shelf life of product as packaged for sale
  3 years from the date of manufacture

- shelf life after dilution or reconstitution according to directions
  Not applicable

- shelf life after first opening the container
  3 years from the date of manufacture.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

200 mg tablets: Blister packages of PVDC (60gsm) coated PVC (250μ)/Aluminium blisters in the following pack sizes: 50, 100, 250, 500, 120, 5000, 84 & 60.

400 mg tablets: Blister packages of PVDC (60gsm) coated PVC (250μ)/Aluminium blisters in the following pack sizes: 50, 56, 60, 100, 250, 500, 2500 & 5000.

800 mg tablets: Blister packages of PVDC (60gsm) coated PVC (250μ)/Aluminium blisters in the following pack sizes: 30, 50, 100, 250, 500, & 28.

6.6 Special precautions for disposal

No special instructions.

7 MARKETING AUTHORISATION HOLDER

BRISTOL LABORATORIES LIMITED
Unit 3, Canalside, Northbridge Road
Berkhamsted, Herts, HP4 1EG
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0357
PL 17907/0358
PL 17907/0359

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/09/2011

10 DATE OF REVISION OF THE TEXT

16/09/2011
UKPAR Cimetidine 200 mg, 400 mg & 800 mg Film-Coated Tablets

PATIENT INFORMATION LEAFLET

CIMETIDINE 200mg, 400mg & 800mg FILM-COATED 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. 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 Cimetidine Tablets are and what they are used for
2. Before you take Cimetidine Tablets
3. How to take Cimetidine Tablets
4. Possible side effects
5. How to store Cimetidine Tablets
6. Further information

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

The name of your medicine is Cimetidine film-coated Tablets referred to as Cimetidine Tablets in the leaflet. It contains the active ingredient called Cimetidine.

Cimetidine belongs to a group of medicines called H2-antagonists. It works by preventing your stomach from producing too much acid.

The tablets are used to:
- Treat and prevent ulcers in your stomach and the first part of your small intestine;
- Prevent acid coming up your throat;
- Prevent your stomach from producing too much acid which could cause pain and discomfort, such as heartburn, indigestion or dyspepsia;
- Prevent acid coming up from the stomach during childbirth;
- Prevent ulcers caused by stress;
- Prevent bleeding from ulcers;
- Prevent general anaesthesia in patients at risk from stomach acid being leaked into the air passages (Mendelson's Syndrome), particularly pregnant patients during labour;
- Reduce mucosal and fluid loss in short bowel syndrome.

You should ask your doctor if you are unsure why you have been given Cimetidine tablets.

2. BEFORE YOU TAKE CIMETIDINE TABLETS

Do not take Cimetidine Tablets if you:
- have an allergy to cimetidine, or any of the other ingredients listed at the end of this leaflet;
- have kidney disease;
- have recurrent dyspepsia (pain and discomfort in the upper part of your stomach) and have not yet seen your doctor about these symptoms.

...
initial dose of 400mg at the start of labour may be followed by doses of 200mg every 2 hours to a maximum of 1.6g may be used.

**Prevention of gastrointestinal bleeding due to stress ulcers in seriously ill patients**

Usual starting dose is a maximum of 2.4g per day given as divided doses to maintain the gastric pH above 4.

**Short bowel syndrome.**

The usual dose of 400mg twice daily may be used.

**Children**

The usual dose for children over one year old is 20 to 30 mg/kg daily in divided doses. However an alternative dosage form e.g. suspension may be more appropriate. It is important to take the tablets at the right times; swallow the tablets with a little water. Always take Cimetidine Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are still not sure.

**If you take more Cimetidine Tablets than you should**

Immediate medical advice should be sought in the event of taking too many tablets or an overdose, even if you feel well.

**If you forget to take Cimetidine Tablets**

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally. Do not take a double dose to make up for a missed dose. If you have any further questions on how to take Cimetidine Tablets, 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 your chest suddenly feels tight and you start to wheeze or get a skin rash or swelling of the face, lips, throat and eyelids. Check with your doctor as soon as possible if any of these side effects are noticed:

- Headache
- Dizziness
- Diarrhoea
- Skin rashes
- Tiredness
- Breast enlargement
- Reversible liver damage
- Muscle and joint pain
- Effects on the kidneys, pancreas, heart and on blood cell counts
- Hair loss (alopecia)
- Impotence
- Confusion, mainly in elderly or very ill patients.

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.

**5. HOW TO STORE CIMETIDINE TABLETS**

Keep out of the reach and sight of children. Do not store above 25°C. Do not use Cimetidine Tablets after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

If you have Cimetidine Tablets left, return them 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. FURTHER INFORMATION**

**What is in Cimetidine Tablets?**

Each 200mg Tablet contains 200mg of the active ingredient cimetidine. The other ingredients are Starch, Povidone, Magnesium Stearate, Sodium Starch Glycolate, Purified Water. Opadry Oy-8339 (E104, E132, E171, E172).

Each 400mg Tablet contains 400mg of the active ingredient cimetidine. The other ingredients are Starch, Povidone, Magnesium Stearate, Sodium Starch Glycolate, Purified Water. Opadry Oy-8339 (E104, E132, E171, E172).

Each 800mg Tablet contains 800mg of the active ingredient cimetidine. The other ingredients are Starch, Povidone, Magnesium Stearate, Sodium Starch Glycolate, Purified Water. Opadry Oy-8339 (E104, E132, E171, E172).

Cimetidine 200mg Tablets are pale green, circular biconvex, film-coated tablets plain on one side and embossed “CIM 200” on the reverse.

Pack sizes: 50, 100, 250, 500, 1200, 2000, 84 and 69 tablets. Not all pack sizes may be marketed.

Cimetidine 400mg Tablets are pale green, oblong, film-coated tablet plain on one side and embossed “CIM 400” on the reverse.

Pack sizes: 50, 56, 60, 100, 250, 500, 2500 and 3000 tablets. Not all pack sizes may be marketed.

Cimetidine 800mg Tablets are pale green, oval, film-coated tablet plain on one side and embossed “CIM 800” on the reverse.

Pack sizes: 28, 30, 50, 100, 230, 500 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

MA Holder: Bristol Laboratories Ltd
Unit 3, Canalside Road, Northbridge Road, Berkhamsted, Herts, HP4 1EY UK.

Manufacturer: MEDRECHI PLC
9 Royal Parade, Kew Gardens, Surrey TW9 3QD UK.

Telephone: 0044(0)1422 200922
Fax: 0044(0)1422 873717
Email: info@bristol-labs.co.uk

Cimetidine 200mg Film-Coated Tablets; PL 17907/0357
Cimetidine 400mg Film-Coated Tablets; PL 17907/0358
Cimetidine 800mg Film-Coated Tablets; PL 17907/0359

This leaflet was last revised in August 2011

To request a copy of this leaflet in Braille, large print or audio format, contact the licence holder at the address for telephone, fax, email above.

19
LABELLING

Cimetidine 200 mg Film-Coated Tablets

Carton for blisters
<table>
<thead>
<tr>
<th>UKPAR Cimetidine 200 mg, 400 mg &amp; 800 mg Film-Coated Tablets</th>
<th>PL 17907/0357-9</th>
</tr>
</thead>
</table>

Blister foil

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Cimetidine 400 mg Film-Coated Tablets

Carton for blisters

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Cimetidine 800 mg Film-Coated Tablets

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**UKPAR Cimetidine 200 mg, 400 mg & 800 mg Film-Coated Tablets**

**PL 17907/0357-9**

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