SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Cimetidine Tablets 800mg

2. Qualitative and Quantitative Composition

Cimetidine USP 800mg

3. Pharmaceutical Form

Tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cimetidine tablets are indicated for the oral treatment of benign gastric and duodenal ulcerations, stomal ulcer, reflux oesophagitis, Zollinger-Ellison syndrome, other conditions where gastric acid reduction is beneficial.

4.2. Posology and Method of Administration

The usual adult doses are 400mg twice daily (with breakfast and at night) or 200mg 3 times daily and 400mg at night or 800mg as a single daily dose at night. Doses should be taken for at least 4 weeks (6 weeks in gastric ulceration); when necessary the dose may be increased to 400mg 4 times daily or rarely to a maximum of 2.4g daily in divided doses to maintain intragastric pH above.

Doses of 20 - 40mg/kg in divided doses have been used in children.

The usual maintenance dose is 400mg at night or 400mg morning and night.

In reflux oesophagitis and Zollinger-Ellison syndrome the dose is 400mg 4 times daily (continued in reflux oesophagitis for 8 weeks).

In obstetrics the dose is 400mg at start of labour, then 200mg every 2 hours to a maximum of 1.6g. In surgical procedures (prophylaxis of acid aspiration) 400mg 90 - 120 minutes before induction of anaesthesia supplemented when necessary.

A 1g daily dose in divided doses to reduce malabsorption and fluid loss is used in short-bowel syndrome; and similar dose used in patients receiving pancreatic enzyme supplements.

Cimetidine tablets are given orally.

4.3. Contra-indications

There are no known contraindications to Cimetidine.

4.4. Special Warnings and Precautions for Use

Care should be exercised in patients with renal and hepatic impairment.

4.5. Interactions with other Medicaments and other forms of Interaction

Cimetidine retards the oxidative phase of hepatic drug metabolism by binding to microsomal cytochrome P450. Clinical effects due to the potentiation of drugs such as benzodiazepines and some beta-adrenoceptor blocking agents are unlikely to be noticed, but may be important where drugs such as phenytoin, warfarin and aminophylline are in use, where the margin between toxic and therapeutic concentrations are small.

4.6. Pregnancy and Lactation

Cimetidine is not recommended for use in pregnancy or during breast feeding.

4.7. Effects on Ability to Drive and Use Machines

None known.

4.8. Undesirable Effects

The drug is well tolerated and symptomatic side effects are rare. Cimetidine binds to androgen receptors, occasionally causes gynaecomastia and may, rarely, cause impotence. Confusion which rapidly reverses on stopping treatment, is also described particularly in elderly and severely ill patients. Acute pancreatitis or thrombocytopenia may occur rarely and interstitial nephritis is another well described but rare effect. Headache, constipation, and nausea have been reported occasionally. In addition, some temporary increases in serum transaminases and gamma glutamyl transpeptidases have occurred. Anaphylactoid reactions have occurred rarely. In a few patients decreases in white blood cell counts and thrombocytopenia have occurred.

Reports of diarrhoea, rash and photosensitivity with the drug are of doubtful significance. Evidence that hypochlorhydria induced by H_2 receptor blockade allows nitrosamine formation in the stomach and so could predispose to gastric cancer has been contested, and no coherent evidence exists to show that any clinical hazard arises.

4.9. Overdose

Vomiting should be induced and/or gastric lavage should be performed. Symptomatic and supportive treatment should be provided.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cimetidine is a histamine H2 receptor antagonist which inhibits both basal and stimulated gastric acid secretion and reduces pepsin output. It has also been shown to inhibit actions of histamine mediated by H2 receptors.

5.2. Pharmacokinetic Properties

Cimetidine is absorbed from the gastro-intestinal tract and peak plasma concentrations are obtained about an hour after administration on an empty stomach and about 2 hours after administration with food. The duration of action is reported to be prolonged by administration with food. Over two-thirds of a dose is excreted in the urine within 24 hours.

5.3. Preclinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to that included in the other sections of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Starch Glycollate BP
Povidone K29-32 BP
Magnesium Stearate BP
Purified Water BP

COATING

Opadry OY-S-8826 HSE
Purified Water BP
Carnauba Wax BP

OPADRY OY-S-8826 INDIVIDUAL EXCIPIENTS

Hydroxypropylmethylcellulose BP
Hydroxypropylcellulose USNF
Titanium Dioxide BP
Polyvinylpyrrolidone USP
Polyethylene Glycol 400 USNF
Iron Oxide Yellow E172
Indigo Carmine Aluminium Lake E132
Iron Oxide Black E172

6.2. Incompatibilities

None known

6.3. Shelf Life

Securitainers - 24 months
Blisters - 60 months

6.4. Special Precautions for Storage

Store below 25ºC.

6.5. Nature and Contents of Container

PVdC blister/foil strips containing 28, 30, 50, 56, 100, 150, 250 and 500 tablets.
Securitainer with white cap and jayfilla ullage filler containing 30, 50, 100, 150, 250 and 500 tablets

6.6. Instruction for Use/Handling

Not applicable

7 MARKETING AUTHORISATION HOLDER

Generics (UK) Limited
Station Close
Potters Bar
Hertfordshire
EN6 1TL

8 MARKETING AUTHORISATION NUMBER(S)

PL 04569/0235

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/07/2007

10 DATE OF REVISION OF THE TEXT

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