GASROL TABLETS

Cimetidine B.P. 200mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Document type: Summary of Product Characteristics

Document status: Final

Release date: 17th August 2020

Number of pages: 6 pages

1. NAME OF THE MEDICINAL PRODUCT

CIMETIDINE 200MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains:

Cimetidine B.P. 200mg

Excipients……..…….... q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

The product is presented as pale Blue biconvex film coated caplet with 'SAM' on one side and 'GASROL 200' on the other side.

This is an Oral tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Cimetidine is indicated in the treatment of duodenal and benign gastric ulceration, including that associated with non-steroidal anti-inflammatory agents, recurrent and stomal ulceration , oesophageal reflux disease and other conditions where reduction of gastric acid by Cimetidine has been shown to be beneficial: persistent dyspeptic symptoms with or without ulceration, particularly meal-related upper abdominal pain, including such symptoms associated with non-steroidal anti-inflammatory agents; the prophylaxis of gastrointestinal 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; and in pancreatic insufficiency to reduce degradation of enzyme supplements. Cimetidine is also recommended in the management of the Zollinger-Ellison syndrome.

4.2 Posology and method of administration.

The total daily dose by any route should not normally exceed 2.4g. Dosage should be reduced in patients with impaired renal function (see Special warnings and precautions for use)

Posology

Adults:

Oral: The usual dosage is 400mg twice a day, with breakfast and at bedtime. For patients with duodenal or benign gastric ulceration, a single daily dose of 800mg at bedtime is recommended. Other effective regimens are 200mg three times a day with meals and 400mg at bedtime (1.0g/day) and, if inadequate, 400mg four times a day (1.6g/day), also with meals and at bedtime.

Elderly:

The normal adult dosage may be used unless renal function is markedly impaired. (see section 4.4).

Paediatric population:

Experience in children is less than that in adults. In children more than one year old, Cimetidine 25-30mg/kg body weight per day in divided doses may be administered by oral route.

The use of Cimetidine in infants fewer than one year old is not fully evaluated; 20mg/kg body weight per day in divided doses has been used.

Method of administration

For oral administration

4.3 Contraindications

Before giving cimetidine to patients with gastric ulcers the possiiblity of malignancy should be excluded since cimetidine may mask symptoms and delay diagnosis. Cimetidine should be given in reduced dosage to patients with impaired renal function.

4.4 Special warnings and precaution for use.

Dosage should be reduced in patients with impaired renal function according to creatinine clearance. The following doses are suggested: Creatinine clearance of 0 to l5ml per minute, 200mg twice a day; 15 to 30ml per minute, 200mg three times a day; 30 to 50ml per minute, 200mg four times a day; over 50 ml per minute, normal dosage. Cimetidine is removed by haemodialysis, but not to any significant extent by peritoneal dialysis.

Clinical trials over six years' continuous treatment and more than 15 years' widespread use have not revealed unexpected adverse reactions related to long-term therapy.

The safety of prolonged use is not fully established and care should be taken to observe periodically patients given prolonged treatment.

Care should be taken that patient with a history of peptic ulcer, particularly the elderly, being treated with Cimetidine and a non-steroidal anti-inflammatory agent are observed regularly.

4.5 Interaction with other medicinal product and other forms of interaction.

Cimetidine can prolong the elimination of drugs metabolised by oxidation in the liver. Although pharmacological interaction with numbers of drug such as Diazepam, Propranolol, have been demonstrated. Only those with oral anticoagulants, phenytoin, theophylline and intravenous lidocaine appear, to date, to be of clinical significance. Close monitoring of patients on Cimetidine receiving oral anticoagulants or phenytoin is recommended and a reduction in the dosage of these drugs may be necessary.

4.6 Pregnancy and Lactation.

Although clinical tests evidence have not revealed any hazards from the administration of Cimetidine during pregnancy or lactation. As with most drugs, the use of Cimetidine should be avoided during pregnancy and lactation unless it is essential.

4.7 Effect on the ability to drive and use machine.

Not applicable.

4.8 Undesirable effect.

Adverse experiences with cimetidine that is common such as Diarrhoea, Skin rashes, Headache, dizziness and uncommon are Gynaecomastia and reversible impotence which is very rare.

4.9 Overdose.

Treatment should consist of gastric lavage or emesis induction, provided that not more than 4 hours has elapsed since ingestion of the drug/followed by suportive measures and symptomatic treatment only. Forced diuresis does not appear to enhance the excretion of cimetidine from the body and is therefore not recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

Cimetidine is a histamine H2-receptor antagonist which rapidly inhibits both basal and stimulated gastric secretion of acid and reduces pepsin output. It is a reversible, competitive antagonist, and is used as an anti-ulcer drug. It is highly selective in its action, is virtually without effect on H1 receptors, or indeed on receptors for other autocoids or drugs. Despite the widespread distribution of H2-receptors in the body, Cimetidine interferes remarkably little with physiological functions other than gastric secretion, implying that the extragastric H2-receptors are of minor physiological importance.

5.2 Pharmacokinetic properties.

Cimetidine is rapidly and virtually completely absorbed from the gastro-intestinal tract. Absorption is little impaired by food or by antacids. 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. Peak concentrations in plasma are attained in about 1 to 2 hours. Hepatic first-pass metabolism results in bioavailabilities of about 60% for Cimetidine. The elimination half-life is about 2-3 hours. Cimetidine is eliminated primarily by the kidneys and 60% or more may appear in the urine unchanged; much of the rest is oxidation products. Small amounts are recovered in the stools.

Cimetidine crosses the placental barrier and is excreted in milk. It does not readily cross the blood-brain barrier.

5.3 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Methyl Paraben

Propyl Paraben

Sodium Meta-Bi-sulphate

Purified Talc.

Magnesium Stearate

Gelatine

6.2 Incompatibilities

Unknown

6.3 Shelf-life

30 Months

6.4 Special precautions for storage

Protect from heat and moisture and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Packs in 2 x 10 blisters and put inside a printed carton white and pink folded box.

7. MARKETING AUTHORISATION HOLDER

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2, WESTERN RESERVOIR ROAD,
ILORIN,
KWARA STATE, NIGERIA.
08057075266
sampharmaceuticalltd@gmail.com

8. MARKETING AUTHORISATION NUMBER(S)

04 – 1373.

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 1st June 2021

10. DATE OF REVISION OF THE TEXT

17th August 2025