

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	RECIM-200 TABLETS (Cimetidine 200mg)
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Pack insert

RECIM - 200

(Cimetidine Tablets BP)

COMPOSITION:

Each tablet contains Cimetidine BP 200mg

INDICATIONS

Treatment and maintenance therapy of active duodenal ulcer.

Treatment of benign gastric ulcers.

Treatment of reflux oesophagitis.

Treatment of pathological hyper secretory conditions (Zollinger - Ellison Syndrome)

DOSAGE & ADMINISTRATION

Cimetidine should be administered preferably with meals or at bed time. Doses should be adjusted to individual patient needs & should continue as long as clinically indicated.

Active duodenal ulcer - 200mg thrice daily for 4-6 weeks; Maintenance therapy for duodenal ulcer-400mg once or twice daily for 6 months; active benign gastric ulcer -300mg four times a day; Reflux oesophagitis -400mg t.id for 4/8 weeks. Pathological hyper secretory conditions (such as Zollinger-Ellison Syndrome)-300mg four times a day or as directed by the physician.

CLINICAL PHARMACOLOGY

Cimetidine competitively inhibits the action of histamine at the H₂ receptor antagonist.

ANTISECRETORY ACTIVITY

1. Acid secretion: Nocturnal-cimetidine 800mg at bed time reduces mean hourly H⁺ activity by greater than 85% over eight hour period in duodenal ulcer patients with no effect on day time acid secretion.

2. Pepsin: Oral cimetidine 300mg reduced total pepsin output as result of decrease in volume of gastric juice.

3. Intrinsic Factor: Intrinsic factor secretion was studied with betazole as a stimulant. Oral Cimetidine 300mg inhibited the rise in intrinsic factor concentration produced by betazole, but some intrinsic factor was secreted at all times.

PHARMACOKINETICS

Cimetidine is rapidly absorbed after oral administration and peak levels occur in 45-90 minutes. The half-life is approximately 2 hours. The principal route of excretion is through urine. Following single dose, 48% of the drug is recovered from the urine after 24 hours as the parent compound.

STORAGE

Store in cool dry & dark place.

Keep medicine out of reach of children.

PRESENTATION

Blister pack of 10 x 10 Tablets

MANUFACTURED BY:



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