1. Name of the medicinal product

Neutronorm®

2. Composition

1 capsule contains	200mg cimetidine.
1 retard tablet contains	350mg cimetidine, slow-release.
1 ampoule contains	229mg cimetidine hydrochloride equivalent to 200mg of cimetidine/2ml.

3. Drug form

Capsules and retard tablets for oral administration.
Ampoules for IV injection or infusion.

4. Clinical particulars

4.1. Indications

Neutronorm® 200mg capsules and Neutronorm® retard tablets:
are indicated in all cases of gastrointestinal disturbances requiring reduction in gastric acid secretion, eg:

- acute erosions of the oesophagus, of the stomach or of the duodenum
- gastro-duodenal ulceration; duodenal ulcer, benign round ulcer
- jejunal peptic ulcer
- peptic reflux oesophagitis
- Zollinger-Ellison syndrome

Neutronorm® 200mg ampoules:
are indicated in cases of haemorrhage in the upper gastro-intestinal tract, eg:

- acute erosions of the oesophagus, of the stomach or of the duodenum
- gastro-duodenal ulceration: duodenal ulcer, benign round ulcer

4.2. Dosage

If not otherwise prescribed by the physician

Capsules 200mg

Initial therapy till symptoms are gone	long-term therapy
1 capsule three times daily with meals	2 capsules
2 capsules at bedtime	at bedtime

If this dosage shows little improvement the dose may be increased up to 4 times 2 capsules (with meals and at bedtime).
The maximum daily dose of cimetidine is 2g.

Retard tablets 350mg: to be administered with meals

initial therapy till symptoms are gone	long-term therapy
2 tablets at bedtime, or	1 tablet at bedtime
1 tablet in the morning, 1 tablet at bedtime	

Ampoules 200mg
The ampoule solution can be injected as a single 200mg dose and repeated every 4-6 hours. The maximum daily dose is 1.5g. The infusion dosage is 200mg, given at a rate of 100mg per hour. The total dosage of 200mg should be repeated every 4-6 hours. The maximum infusion rate is 150mg per hour or 2mg per kg of body weight per hour.
Continuous infusions should be given at a rate of 75mg per hour. The maximum daily dose is 1.5g.

4.3. Contraindications

Hypersensitivity to cimetidine.
In patients with limited renal function the dose should be reduced according to the renal impairment. In severe cases 200mg over a period of 12 hours is adequate. Neutronorm® is hemodialyzable. As a rule, treatment of children is not indicated. However, if the physician deems Neutronorm® treatment necessary, a daily dosage of 20-40mg per kg of body weight in 4 separate doses is recommended.

4.4. Warnings and precautionary measures

During long and serious ulcers (eg duodenal ulcer) the therapy with Neutronorm® should not be abruptly stopped but slowly tapered off. Long-term therapy requires blood count and liver function check-ups.

4.5. Drug interactions and incompatibilities

In some patients who are simultaneously treated with cimetidine and oral anticoagulants, a prolonged prothrombin time has been observed. For this reason monitoring these patients has been recommended. Dose adjustment of anticoagulants may be necessary, if both therapies are simultaneously prescribed. Cimetidine inhibits the oxydative catabolism of drug compounds in the liver microsomes; for this reason interactions with substances eg ß-blockers (propranolol) are possible.

New experiments have shown that by intravenous administration of benzodiazepines and simultaneous cimetidine therapy an increased half-life of benzodiazepines is possible. The clinical relevance of these observations is still uncertain, but caution is recommended.

If antacids containing aluminium magnesiumhydroxide are taken simultaneously with Neutronorm® absorption of cimetidine is reduced. If both medicines are prescribed, they should be administered at least one hour apart.

4.6. Pregnancy and lactation

For reasons of basic medical considerations, the use of Neutronorm® during pregnancy and lactation should be restricted to cases in which administration of the drug is vital.

4.7. Side effects

In rare cases temporary diarrhea, sore muscles, dizziness, and skin rashes can occur during treatment. In general, continuation of therapy is not hindered by these effects. In a few instances, especially in patients suffering from Zollinger-Ellison syndrome as well as after long-term treatment, a gynecomastia has been observed. Occasionally the serum creatinine and transaminase levels are temporarily elevated.

5. Properties and efficacy

Neutronorm®, a single-entity drug of a new class of substances, acts to competitively inhibit histamine H2-receptors and thereby the basal as well as stimulated secretion of gastric acid. It also reduces the pepsin volume.

6. Pharmaceutical particulars

6.1. Storage

Store at room temperature not over 25°C, away from light.
Keep in a safe place out of the reach of children.

6.2. Presentation and packs

Neutronorm® 200mg capsules: 1 box with 20 or 50 capsules,
Neutronorm® retard tablets: 1 box with 20 or 50 retard tablets.
Neutronorm® 200mg ampoules: 1 box with 5 ampoules of 2ml.
Other pack sizes are available.

7. Manufacturer

EBEWE Pharma Ges.m.b.H. Nfg.KG, A-4866 Unterach, AUSTRIA

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