Only for the use of Medical Professionals

Novatac®

Description
Novatac® is a chemically novel competitive H2 receptor antagonist with a guanidinothiazole ring. Is rapidly absorbed with dose related peak plasma concentrations reached in one to three hours. When used as recommended there was no accumulation effect with repeated doses.

Indications:
- Duodenal ulcer
- Maintenance of prevention of recurrence of duodenal ulcer
- Benign gastric ulcer
- Zollinger-Ellison syndrome

Dosage and administration:
***Adult dosage*:** In benign gastric and duodenal ulceration, the dose one Novatac® 40mg tablet at night. It is not necessary to time the dose in relation to meals. Bioavailability of Novatac® is not clinically affected by food in stomach. In all cases clinical response of the patient should be taken into consideration.

Duodenal ulcer: The recommended initial dose is one Novatac® 40mg tablet at night. Treatment should continue for 4-8 weeks. In most patients, healing occurs on this regimen within 4 weeks. In those patients whose ulcers have not healed completely after 4 weeks a further 4 weeks period of treatment is recommended.

Maintenance of prevention of recurrence of duodenal ulcer: One Novatac® 20mg tablet at night. The 20mg dose has been effectively continued in clinical studies of 12 months duration.

Benign gastric ulcer: One Novatac® 40mg tablet at night. Treatment should continue for 4-8 weeks unless endoscopy reveals earlier healing.

Zollinger-ellison syndrome: Patients without prior antisecretory therapy should be started with Novatac® 20mg tablet every six houlrly. Dosage should then be adjusted to individual response Doses up to 800mg daily have been used up to one year without the development of significant adverse effects or tachyphylaxis. Patiens who have been receiving another H2 antagonist may be switched directly to Novatac® at a dose higher than that recommended for new cases. This starting dose will depend on the severity of the condition and the last dose of H2 antagonist previously used.

Use in elderly
The recommended dosage in most elderly patients is the same as in younger patients for all indications. No change in the incidence or type of side effects were seen in treated elderly patients.

Use in elderly
The efficacy and safety of Famotidine in children have not been established.

Use in pregnancy
Famotidine is not recommended for use in pregnancy and should be prescribed only if clearly needed.

Use in lactating mother
Famotidine is secreted in human milk, therefore lactating mothers should either stop breast feeding or stop taking the drug.

Paediatric Use
The safety and effectiveness of Rabeprazole in pediatric patients have not been established.

Geriatric use
No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

Precautions
Gastric carcinoma: Gastric malignancy should be excluded prior to initiation of therapy of gastric ulcer with Famotidine. Use in impaired renal function: Since Famotidine is excreted primarily by the kidney, caution should be observed. The dose should be reduced to 20mg at night if creatinine clearance falls below 10ml/min.

Side effects
Famotidine is generally well tolerated. Headache, dizziness, constipation and diarrhea ha.ve been reported rarely and nausea. Other side effects e.g., dry mouth, nausea, vomiting, abdominal discomfort or distension, anorexia, cholestatic jaundice, anaphylaxis, angioedema, arthralgia have been reported even less frequently.

Contra-indications
Famotidine is contra-indicated in patients with known hypersensitivity to Famotidine or to any component of the formulation.

Overdose
There has been no experience to date with overdosage. Incase of overdosage, the usual measures to remove unabsorbed material from the gastro-intestinal tract, clinical monitoring and supportive therapy should be employed.

Warnings
Clarithromycin should not be used in pregnant womem except in clinical circumstances where no alternative therapy is appropriate. If pregnancy occurs while taking clarithromycin, the patient should be appraised of the potential hazards to the fetus. Amoxycillin: serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens.

Drug Interactions
No clinically important drug interactions have been identified. Famotidine does not interacti with the cytochrome P450 (CYP450)-linked drug metabolizing enzyme system.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light & moisture.

Package quantities
Novatac® 20 Tablets: Carton of 100 tablets in blister. Novatac® 20 Tablets: Carton of 100 tablets in blister.

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