INFORMATION FOR

HEALTH PROFESSIONALS

Data Sheet

DE-NOL™

Tri-Med Distributors P/L., 105 Hay Street, Subiaco. WA 6008.
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Website: http.www.trimed.com.au

Colloidal bismuth subcitrate 120mg tablet

Presentation

Creamy white, round, convex tablets, inscribed gbr 152, diameter 10mm, thickness 5mm, and containing colloidal bismuth subcitrate (CBS) equivalent to 120mg bismuth trioxide (Bi_2O_3). Average weight 430mg.

Uses

Actions

After ingestion of DE-NOL, the bismuth derivatives formed in the acid environment of the stomach bind strongly to the proteins in ulcerated tissue to form a protective layer which shields it from aggressive factors and allows it to heal. In addition DE-NOL brings about an increase in local prostaglandin levels, which stimulates the production of bicarbonate and mucin thereby also protecting the stomach. In vitro and in vivo DE-NOL is active against Helicobacter (H) pylori, an organism which causes gastritis and is closely associated with ulcer recurrence. Healing of the underlying gastritis by eradication of H.pylori prevents ulcer relapse. DE-NOL may be combined with amoxicillin or nitroimidazoles in order to improve eradication rates of H.pylori, while triple therapy including DE-NOL, tetracycline or amoxicillin and metronidazole has given the best results.

Pharmacokinetics

Although DE-NOL is a locally active agent, minute quantities of bismuth derived from CBS (less than 0.2% of the dose) are absorbed during therapy. The urinary clearance of bismuth is approximately 50ml/min. The vast bulk of ingested bismuth is excreted with the faeces. Absorbed bismuth is excreted in the urine and blood levels decline rapidly after completion of therapy. However, the intermediate half-life of 5-11 days represents most of the clearance and elimination.

Indications

Duodenal and gastric ulceration.

Non-ulcer dyspepsia due to H.pylori associated gastritis, when used in conjunction with antibiotic therapy.

DE-NOL, in combination with tetracycline and metronidazole is indicated for the eradication of H.pylori infection or H.pylori infection associated with non-ulcer dyspepsia in a 14 day treatment programme.

Dosage and Administration

Two tablets with breakfast and two tablets with dinner or at bedtime. Alternatively, one tablet with the three main meals and again before going to bed. The tablets should be taken with some water. DE-NOL can be taken in this way for up to a maximum of 2 months when necessary. This should be followed by a 2 month period free of bismuth containing preparations before another course of therapy can be given.

Contraindications

In severe renal impairment, DE-NOL should be avoided.

Warnings and Precautions

Prolonged and excessive use of bismuth compounds in the past has occasionally led to reversible encephalopathy. This does not occur with DE-NOL when used as advised.

The use of other bismuth containing agents concomitantly is not recommended.

Use During Pregnancy and Lactation

There is insufficient information available on the use of DE-NOL during pregnancy and lactation for an assessment of possibly harmful effects although studies in animals have not indicated the presence of any deleterious effects.

Effects on Ability to Drive and Use Machines

No effects from DE-NOL are to be expected.

Adverse Effects

Blackening of the stools can occur due to the formation of bismuth sulphide but this can be easily distinguished from melaena. Other effects are mainly gastrointestinal in nature and include nausea, vomiting, constipation and diarrhoea. A few cases of mild allergic reaction have been reported.

Interactions

No other medicines, food or drink should be consumed within half an hour before or after a dose of DE-NOL as they could theoretically interfere with its reaction with the ulcer. The absorption of tetracycline may be reduced if this is given concomitantly with DE-NOL.

Overdosage

Symptoms

Acute, massive overdose may lead to reversible renal failure with a delayed onset of up to 10 days.

Treatment

Immediate treatment with gastric lavage and repeated doses of activated charcoal suspension combined with the use of saline laxatives should be given in all such cases. Blood and urine bismuth levels should be monitored as well as renal function. Further treatment is basically symptomatic.

Chelation therapy with dimercaptosuccinic acid (DMSA), or dimercapto-propanesulfonic acid (DMPS) may be considered when high bismuth blood levels with signs of renal dysfunction occur. Where these medicines are unavailable, Dimercaprol may be used. In severe renal failure additional haemodialysis is indicated.