

Gastro-Soothe

Hyoscine-N-butylbromide 10mg tablet

Presentation

White, circular biconvex film coated tablet plain on both the sides.

Uses

Actions

GASTRO-SOOTHE exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and urinary tracts. As a quaternary ammonium derivative, hyoscine-N-butylbromide does not enter the central nervous system. Therefore, anticholinergic side effects at the central nervous system do not occur. Peripheral anticholinergic effects result from a ganglion-blocking action within the visceral wall as well as from anti-muscarinic activity.

Pharmacokinetics

As a quaternary ammonium compound, hyoscine-N-butylbromide is highly polar and hence only partially absorbed following oral (8%) administration and the systemic availability was found to be less than 1%. Nevertheless, despite the briefly measurable low blood levels, hyoscine-N-butylbromide and/or its metabolites have been observed at the sites of action.

The half-life of the terminal elimination phase $t_{1/2\gamma}$ is approximately 5 hours. The total clearance is 1.2 l/min, approximately half the clearance is renal. The main metabolites found in urine bind poorly to the muscarinic receptor. Hyoscine-N-butylbromide does not pass the blood-brain barrier and plasma protein binding is low.

Indications

Muscle spasm of the gastrointestinal tract.

Dosage and Administration

Adults and children over 6 years: 2 tablets (20 mg) four times a day. The tablets should be swallowed whole with adequate fluid.

Contraindications

GASTRO-SOOTHE is contraindicated in myasthenia gravis, megacolon and in patients who have demonstrated prior sensitivity to the product.

Warnings and Precautions

Because of the potential risk of anticholinergic complications, GASTRO-SOOTHE tablets should be administered with caution in patients susceptible to narrow angle glaucoma, intestinal or urinary outlet obstruction, and those inclined to tachyarrhythmia.

Elevation of intraocular pressure may be produced by the administration of anticholinergics such as GASTRO-SOOTHE in patients with undiagnosed and therefore untreated narrow angle glaucoma.

Pregnancy and Lactation

Long experience has shown no evidence of ill effects during human pregnancy. Preclinical studies in rats and rabbits did not show either embryotoxic or teratogenic effects. Hyoscine-N-butylbromide is classified with medications that have been taken by only a limited number of pregnant women but without an increase to the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. However, the usual precautions regarding the use of drugs at this time, especially during the first trimester, should be observed.

Safety during lactation has not yet been established, however, adverse effects on the new born have not been reported.

Effects on Ability to Drive and Use Machines

In rare cases GASTRO-SOOTHE may cause drowsiness, if affected, patients should not drive or operate machinery.

Adverse Effects

Anticholinergic side effects including xerostomia, dyshidrosis, tachycardia, visual accommodation disturbances, and potentially urinary retention may occur but are generally mild and self-limiting.

There have been rare reports of dizziness, drop in blood pressure, and flushing.

Hypersensitivity reactions including skin reactions, dyspnoea, anaphylactoid reactions and anaphylactic shock have been reported very rarely.

Interaction

The anticholinergic effect of tricyclic antidepressants, antihistamines, quinidine, amantadine and disopyramide may be intensified by GASTRO-SOOTHE.

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.

The tachycardic effects of beta-adrenergic agents may be enhanced by GASTRO-SOOTHE.

Overdosage

Symptoms

Serious signs of poisoning following acute overdosage have not been observed in man. In case of overdose, anticholinergic symptoms such as urinary retention, dry mouth, reddening of skin, tachycardia, inhibition of gastrointestinal motility, and transient visual disturbances may occur.

Therapy

In the case of oral poisoning, gastric lavage with activated charcoal should be followed by magnesium sulphate (15%). Symptoms of GASTRO-SOOTHE overdosage respond to parasympathomimetics. For patients with glaucoma, urgent ophthalmological advice should be sought and pilocarpine should be given locally. If necessary, parasympathomimetics should be administered, e.g. neostigmine 0.5-2.5 mg i.m. or i.v. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration should be considered. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

Pharmaceutical Precautions

Store below 30 °C

Store in a safe place out of the reach of children.

Medicine Classification

Pharmacist only medicine

Package Quantities

Tender blister pack of 20 tablets
OTC blister pack of 20 tablets

Further Information

Excipients

Lactose, maize starch, microcrystalline cellulose, Methocel A4C, Sodium starch glycolate, Colloidal Anhydrous Silica, Magnesium stearate, hydroxyl propyl methyl cellulose, polyethylene glycol, Talc, titanium dioxide

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