

BUSTON
Hyoscine-N-Butylbromide 20mg/ml Solution for injection

Description

A colourless to slightly yellow clear sterile solution in amber glass ampoules.

Composition

Each ml ampoule contains 20mg of Hyoscine-N-butylbromide.

Mode of Action

Hyoscine and related compounds are competitive antagonists of the actions of acetylcholine and other muscarinic agonist; they compete with such agonists for a common binding site on the muscarinic receptor. The receptors affected are those of peripheral structures that are either stimulated or inhibited by muscarine, which are exocrine glands and smooth and cardiac muscle.

Summary of pharmacodynamics and pharmacokinetics

Buston is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs.

After intravenous administration hyoscine-N-butylbromide is rapidly distributed into the tissues. The volume of distribution (V_{ss}) is 128 l. 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 of the clearance is renal.

In rat, highest concentrations of hyoscine-N-butylbromide are found in the tissue of the gastrointestinal tract, liver and kidneys. Plasma protein binding of hyoscine-N-butylbromide is low.

Hyoscine-N-butylbromide does not readily pass the blood-brain barrier.

Indications

Buston 20mg/ml Solution for Injection is indicated in the treatments of symptomatic relief of gastro-intestinal or genitor-urinary disorders characterized by smooth muscle spasm.

Adverse reactions/side effects

Side effects of Buston are dryness of the mouth, increased viscosity of bronchial secretions, accommodation disorders, diminution of lacrimal secretion, tachycardia, palpitations, constipations, urinary retention, excitement, irritability, mental confusion of the elderly.

Precautions/warnings

In prostatic hypertrophy, coronary insufficiency, rhythm disorder, hyperthyroidism, chronic bronchitis due to the increase of viscosity of bronchial secretions, paralytic ileus, intestinal atony of the elderly, toxic megacolon, mental alertness and driving or machinery operation eventual disorders of accommodations, pregnant women (particularly at the end of pregnancy), lactating women (avoid breastfeeding when using Hyoscine-N-butylbromide injection) and in elderly with impaired metabolic, liver and kidney function.

Contraindications

Buston is contraindicated in patients with hypersensitivity to hyoscine-N-butylbromide, prostatic enlargement, paralytic ileus or pyloric stenosis, closed-angle glaucoma or narrow angle between the iris and the cornea, porphyria. Not recommended for children.

Dosage and directions for use

Buston 20mg/ml Solution injections may be administered by Intramuscular or intravenous injection.

1 ampoule (20 mg) should be given IM or IV, repeated after 30 minutes or necessary, up to a maximum of 100 mg daily or as prescribed by the physician.

Not recommended for children under 12 years old.

Incompatibility

Buston should not be combined with other aqueous solutions of medicaments.

Use in pregnancy and lactation

Although Buston has been in wide general use for many years, there is no definitive evidence of ill-consequence during human pregnancy; animal studies have shown no hazard. Nevertheless, medicines should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

Safety during lactation has not yet been established.

Drug interactions

Take into account of the synergism of anticholinergic effects in case of concomitant administration of other atropinic drugs such as anticholinergic, antiparkinson drugs, Imipraminic antidepressant and phenothiazinic neuroleptic, H₁-antihistamine, Disopyramine.

Overdosage, symptoms and treatmentSymptoms

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

Therapy

Symptoms of Buston overdosage respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis, intubation and artificial respiration. Catheterisation may be required for urinary retention.

In addition, appropriate supportive measures should be used as required.

Presentation

This injection is available in 1ml ampoules
10 ampoules are packed into one paper box.

Storage conditions

Protect from light and store below 30°Celsius. Keep out of reach of children.

Shelf-life

The injections can be used within 60 months from the date of manufacture if kept as recommended.

Registration number

BUSTON MAL 200XXXXXA

Manufactured by

Siu Guan Chem. Ind. Co., Ltd.

No. 128 Shin Min Road, Chia Yi, Taiwan.

Tel: 05-2360636

Fax: 05-2223961

Imported by

Averroes Pharmaceuticals Sdn. Bhd.

11E, Level 5, Block 1

Worldwide Business Center

Jalan 13/50, Section 13

40000 Shah Alam

Malaysia

Tel : +603 5511 8928

Fax: +603 5511 8918

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