HYOSCINE-N-BUTYLBROMIDE

ADUSCINE
20mg/mL solution for injection (I.M./I.V)

ANTICHOLINERGIC

FORMULATION:
Each ampoule of 1mL contains of Hyoscine Butylbromide........... 20mg

INDICATIONS:
Hyoscine-N-Butylbromide is an antispasmodic agent, indicated in acute spasms of the urogenital tract and the digestive tract (colics, ulcers and severe gastritis). It can also be used to reduce spasm in diagnostic procedures such as gastro-duodenal endoscopy.

DOSEAGE:
Administer by intramuscular or intravenous injection.
- Adults: 20mg
- Children under 15 years: 5mg

Administered can be repeated after 30 minutes when necessary. Hyoscine-N-Butylbromide injection may be diluted with Dextrose 5 % or with Sodium Chloride 0.9 % Solution for Infusion.

PREGNANCY AND BREAST-FEEDING:
No harmful effects of Hyoscine-N-Butylbromide used during pregnancy or breast feeding are known.

Interactions
The sedative effect of hyoscine may be enhanced by alcohol or other CNS depressants.

Pharmacokinetics
Hyoscine is readily absorbed from the gastrointestinal tract after oral doses of the hydrobromide. It is almost entirely metabolised, probably in the liver; only a small proportion of an oral dose is excreted unchanged in the urine. It crosses the blood-brain barrier and has been stated to cross the placenta. Hyoscine is also well absorbed after application to the skin.

The quaternary derivatives, such as the butylbromide or methobromide, are poorly absorbed from the gastrointestinal tract and do not readily pass the blood-brain barrier.

Precautions:
Hyoscine-N-Butylbromide should be used with caution in children and the elderly, who may be more susceptible to its adverse effects. It is contra-indicated in patients with prostatic enlargement, in whom it may lead to urinary retention, and in those with paralytic ileus or pyloric stenosis. In patients with ulcerative colitis its use may lead to ileus or megacolon, and its effects on the lower oesophageal sphincter may exacerbate reflux. Caution is generally advisable in any patient with diarrhea. It should not be given to patients with myasthenia gravis except to reduce adverse muscarinic effects of an anticholinesterase.

Hyoscine-N-Butylbromide should not be given to patients with angle-closure glaucoma or with a narrow angle between the iris and the cornea, since it may raise intra-ocular pressure and precipitate an acute attack. Acute angle-closure glaucoma has been reported in patients receiving nebulised Hyoscine-N-Butylbromide. Some manufacturers recommend that Hyoscine-N-Butylbromide eye drops should not be used in infants aged less than 3 months due to the possible association between the induced cycloplegia and the development of amblyopia. Systemic reactions have followed the absorption of Hyoscine-N-Butylbromide from eye drops; overdosage is less likely if the eye ointment is used. In the event of blurred vision after topical administration of Hyoscine-N-Butylbromide to the eye patients should not drive or operate machinery. Systemic administration of antimuscarinics may also cause blurred vision, dizziness, and other effects that may impair a patient’s ability to perform skilled tasks such as driving.

Because of the risk of provoking hyperthermia, Hyoscine-N-Butylbromide should not be given to patients, especially children, when the ambient temperature is high. It should also be used cautiously in patients with fever.

Hyoscine-N-Butylbromide and other antimuscarinics need to be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, heart failure, and in cardiac surgery, where they may further accelerate the heart rate. Care is required in patients with acute myocardial infarction, as ischaemia and infarction may be made worse, and in patients with hypertension.

Hyoscine-N-Butylbromide may cause confusion, especially in the elderly. Reduced bronchial secretion caused by systemic administration of Hyoscine-N-Butylbromide may be associated with the formation of mucus plugs.

In the treatment of parkinsonism, increases in dosage and transfer to other forms of treatment should be gradual and the antimuscarinic should not be withdrawn abruptly. Minor reactions may be controlled by reducing the dose until tolerance has developed.

Persons with Down’s syndrome appear to have an increased susceptibility to some of the actions of Hyoscine-N-Butylbromide, whereas those with albinism may have a reduced susceptibility.

WARNING:
Do not use Hyoscine-N-Butylbromide in patients with glaucoma, with obstruction of urogenital or digestive tract or with severe cardiac disorders. It may cause somnolence and blurred visions which may impair the ability to drive or operate machines.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescriptions.

ADVERSE EFFECTS: Hyoscine-N-Butylbromide can cause somnolence, constipation, dry mouth, dizziness and rarely tachycardia.

OVERDOSE:
Symptoms: Loss of accommodation, tachycardia, orthostatic hypotension.
Treatment: When necessary, parasympathetic agents, e.g. neostigmine, to reverse parasympatholytic effects.

STORAGE Store at temperature not exceeding 30°C. Protect from light.

PRESENTATION: USP Type I clear glass ampoule (Box of 10’s)

Manufactured by:
ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD.
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P.R. China.

Imported and Distributed by:
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