

AMENDED ARTWORK - PACKAGE INSERT



HYOSCINE BUTYLBROMIDE TABLET 10MG

Each tablet contains:
Hyoscine N-Butylbromide 10mg

Pharmacology:

The effect of Hyoscine on the heart is to alter rate. With small doses, the heart rate decreases temporarily and increases with larger doses. It also reduces the motility and tone of the gastrointestinal tract and may even reduce the volume of its various secretions.

The drug will produce mydriasis and paralysis of accommodation (cycloplegia). Hyoscine butylbromide is poorly absorbed from the gastrointestinal tract. In 10 experiments in 3 volunteers, hyoscine butylbromide in single doses of up to 600mg taken as tablet, appeared to be inactive by mouth, either it remained unabsorbed or it was absorbed more slowly than it was inactivated in the body. After 50 to 100mg of hyoscine butylbromide was given to 6 male volunteers, by mouth or by intra-intestinal infusion, very little hyoscine butylbromide was absorbed from the upper small intestine and none appeared in the plasma. About 2% and 90% of the dose appeared in the urine and faeces respectively. After intravenous administration of 8mg to 1 volunteer, 42% was eliminated in the urine and 37% in faeces.

Indications:

It is indicated for gastrointestinal spasm and hypermotility, biliary dyskinesia and spasm of the urinary tract, delayed relaxation of the lower uterine segment and dysmenorrhoea.

Dosage:

Route of administration : Oral

Adults : One to two tablets, three to four times daily.

Children (6-12 years) : One tablet, three times daily.

Contraindications:

Because of the anticholinergic effect of hyoscine, it should not be used in patients with glaucoma, achalasia, prostatic hypertrophy, or obstruction of the bladder neck. It is contraindicated in patients with myasthenia gravis and in patients known to be hypersensitive to hyoscine.

Precautions:

Since drowsiness, disorientation, and confusion may occur with the use of hyoscine, patients should be warned of the possibility and cautioned against engaging in activities that require mental alertness, such as driving a motor vehicle or operating dangerous machinery.

Potentially alarming idiosyncratic reactions may occur with ordinary therapeutic doses of hyoscine butylbromide. Hyoscine should be used with caution in patients with pyloric obstruction, or urinary bladder neck obstruction. Hyoscine butylbromide should be used with special caution in the elderly or in individuals with impaired metabolic, liver or kidney functions, because of the increased likelihood of CNS effects.

Use in Pregnancy:

Long experience has shown no evidence of ill-effects during human pregnancy. However, the usual precautions regarding the use of drugs in pregnancy, especially during the first trimester, should be observed. Safety during lactation has not been established.

Side Effects:

The side effects of hyoscine butylbromide include dryness of the mouth with difficulty in swallowing, thirst, dilatation of the pupils with loss of accommodation and photophobia, increased intra-ocular pressures, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and arrhythmias, and desire to urinate with the inability to do so, as well as reduction in the tone and motility of the gastrointestinal tract leading to constipation. Occasionally vomiting, giddiness and staggering may occur.

Drug Interactions:

The anticholinergic effect of tricyclic anti-depressants, antihistamines, quinidine, amantadine and diisopyramide can potentiate the anticholinergic effect of Hyoscine butylbromide.

Hyoscine butylbromide enhances tachycardic effects of β -adrenergic agents. Dopamine antagonist, eg metoclopramide reduces effects of both drugs on GIT.

Symptoms and Treatment for Overdosage and Antidote(s):

Overdosage with hyoscine butylbromide may cause disorientation memory disturbances, dizziness, restlessness, hallucinations or confusion.

Treatment : Empty the stomach by aspiration and lavage. The use of charcoal to prevent absorption, followed by lavage has been suggested. Give a purgative, such as 30g of sodium sulphate in 250ml of water. Phystigmine salicylate has been advocated to control the central and peripheral effects of hyoscine but is not now generally recommended. Excitement may be controlled by diazepam or a short acting barbiturate. Supportive therapy may require oxygen and assisted respiration ice bags or alcohol sponges for hyperpyrexia, especially in children, bladder catheterisation and the administration of fluids.

Pack Size: A box : A box of 10 x 10, 50 x 10 and 100 x 10 tablets per strip.

Storage Conditions: Store at or below 30°C. Protect from light.

Shelf-life: 5 years.

Description: Round, white, film-coated tablet.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Revised on March 2019
TL637B-R7

Manufacturer:
SUNWARD PHARMACEUTICAL PTE. LTD.
11, Wan Lee Road,
Singapore 627943.

Product Holder:
SUNWARD PHARMACEUTICAL SDN. BHD.
No. 9, 11 & 17, Jalan Kempas 4,
Taman Perindustrian Tampoi Indah,
81200 Johor Bahru, Johor, Malaysia.