

HYOSUN SYRUP 5MG/5ML

Each 5ml contains:-

Hyoscine N-Butylbromide	5mg
Preservative: Sodium Benzoate	9.5mg

Product Description:

A clear, red syrup with cherry flavour.

Pharmacodynamics:

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 (cyclopegia).

Pharmacokinetics:

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 tablets, 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, a very little hyoscine butylbromide was absorbed from the upper small intestinal and none appeared in the plasma.

Indication:

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.

Recommended Dosage:

Adults: 10ml to 20ml, three to four times daily.

Children (6 - 12 years): 10ml three times daily.

The doses are to be taken half an hour before meals.

Route of Administration: Oral

Contraindications:

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

Warnings and 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 patient 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.

Interactions with Other Medicaments:

The anticholinergic effect of tricyclic anti-depressants, antihistamines, quinidine, amantadine and diisopyramide can potentiate the anticholinergic effect of Hyoscine butylbromide. Hyoscine butylbromide enhances tachycardic effect of beta- adrenergic agents. Dopamine antagonist, eg. Metoclopramide reduces effects of both drugs on GIT.

Pregnancy and Lactation:

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

Side Effects:

The side effects of hyoscine butylbromide include dryness of mouth with difficulty in swallowing, thirst, dilatation of the pupils with loss of accommodation and photophobia, increased intra-ocular pressure, 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 gastro-intestinal tract leading to constipation. Occasionally vomiting, giddiness and staggering may occur.

Symptoms and Treatment of Overdose:

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

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.

Physostigmine salicylate has been advocated to control the central and peripheral effects of hyoscine but is 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.

Effects on Ability to Drive and Use Machine: Not applicable.

Storage Condition for pack size 60ml, 100ml, 120ml, 3.6L and 3.8L:

Store at or below 30°C. Protect from light.

Storage Condition for pack size 1L:

Store at or below 25°C. Protect from light.

Shelf-life: 3 years.

Pack Size: A bottle of 60 ml, 100 ml and 120 ml.

Pack Size (export only): A bottle of 1 litre, 3.6 litres and 3.8 litres.

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

Manufacturer & Product Registration Holder:

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