

SPADIN SYRUP

Composition:

Each 5ml syrup contains Hyoscine-N-butylbromide 5mg.

Description:

Red colored syrup having pleasant fruity flavour.

Actions:

Hyoscine-N-butylbromide is a peripheral anticholinergic/antispasmodic agent. It exerts its antispasmodic actions on the smooth muscles of the gastrointestinal, biliary and genitourinary tracts. As a quaternary ammonium derivative, it does not cross the blood-brain barrier and hence does not exert any central anticholinergic side effects. The peripheral anticholinergic actions of hyoscine-N-butylbromide is the result of its ganglion-blocking action within the visceral wall and its antimuscarinic activity.

Hyoscine-N-butylbromide is a highly polar compound and is poorly absorbed from the gastrointestinal tract. However, high concentrations of the drug and its metabolites are localized in the gastrointestinal tract, gall bladder, bile ducts, liver and kidneys. Hyoscine-N-butylbromide does not readily cross the blood-brain barrier.

Indications:

For the treatment of gastrointestinal tract spasm, genitourinary tract spasm, spasm and dyskinesia of the biliary system.

Contraindications:

Hypersensitivity to hyoscine-N-butylbromide or to any other component of the product, myasthenia gravis, toxic megacolon, paralytic ileus and urinary retention.

Warning and Precautions:

Hyoscine-N-butylbromide should be used with caution in patients who are susceptible to cardiac arrhythmias, tachycardia, narrow angle glaucoma, gastrointestinal or urinary tract obstruction.

Pregnancy and lactation:

As with all drugs, hyoscine-N-butylbromide should be given to pregnant women only when clearly indicated. Safety during lactation has not been established, although adverse effects on the new born have not been reported.

Effects on ability to drive and use machines:

Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

Drug interactions:

Concurrent administration of hyoscine-N-butylbromide with drugs that have anticholinergic effects (such as tricyclic antidepressant, antihistamines, amantadine) may result in increased anticholinergic side effects. Use with beta-adrenergic agents may lead to enhanced tachycardia, while use with metoclopramide may cause mutual antagonism of drug effects.

Dosage & Administration:**Adults & Children more than 12 years old:**

10-20mg (2-4 teaspoonfuls) 3-4 times daily

Children 6 to 12 years old:

10mg (2 teaspoonful) 3 times daily

Route of Administration:

Oral administration

Side-effects:

Side effects are generally mild and self-limiting and may include xerostomia, urinary hesitancy and retention, tachycardia, palpitation and dyshidrosis. Very rarely, hypersensitivity may be manifested, particularly as skin reactions.

Overdosage & Treatment:

In the case of overdosage, gastric lavage with medicinal charcoal, followed by an osmotic laxative (eg magnesium sulfate 15%) should be carried out.

Anticholinergic symptoms such as urinary retention, dry mouth, tachycardia, visual disturbances, inhibition of gastrointestinal motility and glaucoma may occur. These symptoms may be treated with parasympathomimetic agents such as neostigmine 0.5 – 2.5mg IM or IV. Glaucoma may be treated with pilocarpine eye-drops. In case of respiratory paralysis, intubation, artificial respiration should be instituted; cardiovascular symptoms should be treated as appropriate.

Other symptomatic treatment should be instituted accordingly when necessary.

Storage Conditions:

Store below 30°C.

Protect from light.

Keep out of reach of children.

Packaging & Pack Sizes:

Bottles of 60ml and 120ml

Manufactured by:

NORIPHARMA SDN. BHD. 200701034604 (792633-A)

Lot 5030, Jalan Teratai,

5 1/2 Mile off Jalan Meru,

41050 Klang, Selangor

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