

Size : 82 x 190 mm

82.00 mm

190.00 mm

POM

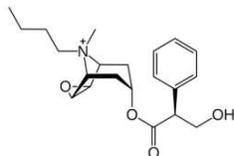
HYOSCINE BUTYLBROMIDE TABLETS BP 10mg

COMPOSITION:

Each film coated tablet contains :
Hyoscine Butylbromide BP 10mg
Excipients q.s.
Colour : Titanium Dioxide BP

DESCRIPTION

Hyoscine Butylbromide Tablets contain Hyoscine Butylbromide.



Hyoscine Butylbromide is white or almost white, crystalline powder. Freely soluble in water and in methylene chloride, sparingly soluble in anhydrous ethanol.

CLINICAL PHARMACOLOGY

It exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genito-urinary tracts. As a quaternary ammonium derivative, hyoscine butylbromide does not enter the central nervous system. Therefore, anticholinergic side effects at the central nervous system do not occur. Peripheral anticholinergic action results from a ganglion-blocking action within the visceral wall as well as from an anti-muscarinic activity.

As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. Because of its high affinity for muscarinic receptors and nicotinic receptors, hyoscine butylbromide is mainly distributed on muscle cells of the abdominal and pelvic area as well as in the intramural ganglia of the abdominal organs. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 4.4%. Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6.2 to 10.6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine.

INDICATIONS AND USAGE

Tablets are indicated for the relief of spasm of the genito-urinary tract or gastrointestinal tract and for the symptomatic relief of Irritable Bowel Syndrome.

DOSAGE AND ADMINISTRATION

Adults: 2 tablets four times daily. For the symptomatic relief of Irritable Bowel Syndrome, the recommended starting dose is 1 tablet three times daily, this can be increased up to 2 tablets four times daily if necessary.
Children 6 - 12 years: 1 tablet three times daily.

CONTRAINDICATIONS

Tablets are contraindicated in:

- patients who have demonstrated prior hypersensitivity to hyoscine butylbromide or any other component of the product
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytic or obstructive ileus
- megacolon
- narrow angle glaucoma

WARNINGS

Tablets should be used with caution in conditions characterized by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery where it may further accelerate the heart rate. Due to the risk of anticholinergic complications, caution should be used in patients susceptible to intestinal or urinary outlet obstructions.

Because of the possibility that anticholinergics may reduce sweating, Buscopan should be administered with caution to patients with pyrexia.

DRUG INTERACTIONS

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. butyrophenones, phenothiazines), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Hyoscine butylbromide tablets.

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract. The tachycardic effects of beta-adrenergic agents may be enhanced by Hyoscine butylbromide tablets.

ADVERSE REACTIONS

Skin reactions, tachycardia, dry mouth, Dyshidrosis, urinary retention

STORAGE :

Store at a temperature below 30° C,
Protect from light & moisture.
Keep out of reach of children.

PACKING :

HYOSCINE BUTYLBROMIDE TABLETS BP 10mg is available in 1000 Tablets Jar.

Manufactured in India by:

ANGEL BIOGENICS PVT. LIMITED

Shapar-Veraval, Dist. Rajkot - 360024

At : PF-23, GIDC Industrial Estate,

Sanand-II, Ahmedabad-382110 (India.)

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