HYOMIDE TABLET 10mg

Hyoscine Butylbromide

DESCRIPTION
A 6.5mm core diameter, round, convex, film coated white tablet marked 'UP' with score on one side.
Each tablet contains Hyoscine Butylbromide 10 mg

INDICATION
Hyomide tablets are indicated in spasm of the gastro-intestinal or genito-urinary tracts, biliary dyskinesia and in the prevention and treatment of spasmodic dysmenorrhea.

PHARMACODYNAMICS
Hyoscine N-butylbromide is a quaternary ammonium derivative anticholinergic and has an antispasmodic effect on the organs of the abdominal and pelvic cavities. It acts by inhibiting the muscarinic actions of acetylcholine on structures innervated by postganglionic cholinergic nerves as well as on smooth muscles that respond to acetylcholine but lack cholinergic innervation.

PHARMACOKINETICS
Hyoscine N-butylbromide, a quaternary ammonium compound, is less lipid soluble than atropine and so may be less likely to cross the blood-brain barrier; it is also poorly absorbed. 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 (10-25%) than it was inactivated in the body. Hyoscine N-butylbromide, a quaternary ammonium compound is less lipid soluble than atropine and so may be less likely to cross the blood-brain barrier; it is also less well absorbed. 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 (10-25%) than it was inactivated in the body.

DOSAGE
Adults
Orally : 1 to 2 tablets, three to four times daily.
In dysmenorrhoea, treatment should commence two days before the expected onset of the period and continue for three days after menstruation has begun.
Children 6 -12 years
Orally : 1 tablet three times daily.

OVERDOSAGE
Features which may be encountered are dry mouth, loss of accommodation, tachycardia, orthostatic, hypotension and Cheyne-Stoke respiration.
Recommended treatment for anticholinergic overdose includes the following:

a) Emesis or gastric lavage with 4% tannic acid solution.
b) Administration of an aqueous slurry of activated charcoal.
c) To reverse severe anticholinergic symptoms, slow, intravenous administration of physostigmine in doses of 0.5 to 2mg (0.5 to 1mg in children up to a total dose of 2mg), at a rate not to exceed 1mg per minute; may be given in repeated doses of 1 to 4 mg as needed, up to a total dose of 5mg in adults. Or, neostigmine methylsulfate administered intramuscularly in doses of 0.5 to 1 mg, repeated every 2 to 3 hours; or intravenously in doses of 0.5 to 2 mg, repeated as needed.
d) To control excitement or delirium, administration of small doses of a short-acting barbiturate (100mg thiopental sodium) or benzodiazepines, or rectal infusion of 2% solution of chloral hydrate.
e) To restore blood pressure, infusion of norepinephrine bitartrate or metaraminol.
f) Artificial respiration with oxygen if needed for respiratory depression.
g) Symtomatic treatment as necessary.

Up-to-date information on treatment of overdose can be obtained from The National Poison Centre, University Sains Malaysia.

TOXICOLOGY
No documented studies on Hyoscine N-butylbromide were available. The following are studies on anticholinergies and Hyoscine overall.

Carcinogenicity and mutagenicity: Documented studies are not available.

Pregnancy/ Reproduction: Hyoscine crosses the placenta. Studies with hyoscine have not been done in animals or humans. FDA pregnancy category: C.

Breast-feeding: In general, anticholinergics may inhibit lactation. As Hyoscine N-butylbromide is an quarternary ammonium compound, it is unlikely that it will be excreted in the breast milk since it is incompletely absorbed from the gastrointestinal tract and have poor lipid solubility.

Porphyria: Hyoscine N-butylbromide has been associated with clinical exacerbations of porphyria and is considered unsafe in porphyric patients.

Pediatrics: Infants and young children are especially susceptible to the toxic effects of anticholinergics. Close supervision is recommended for infants and children with spastic paralysis or brain damage since an increased response to anticholinergics has been reported in these patients and dosage adjustments are often required. When anticholinergics are given to children where the environmental temperature is high, there is a risk of a rapid increase in body temperature because of these medications suppression of sweat gland activity. A paradoxical reaction characterized by hyperexcitability may occur in children taking large doses of anticholinergics.

Geriatrics: Geriatric patients may respond to usual doses of anticholinergics with excitement, agitation, drowsiness, or confusion. They are especially susceptible to the anticholinergics side effects, such as constipation, dryness of mouth, and urinary retention (especially in males). If these side effects occur and continue or are severe, medication should probably be discontinued. Caution is also recommended when anticholinergics are given to geriatric patients, because of the danger of precipitating undiagnosed glaucoma. Memory may become severely impaired in geriatric patients especially those who already have memory problems, with the continued use of anticholinergics since these drugs block the actions of acetycholine, which is responsible for many functions of the brain, including memory functions.

166mm(w) x 180mm (h)

Black 100%

Dental: Prolonged use of anticholinergics may decrease or inhibit salivary flow, thus contributing to the development of caries, periodontal disease, oral candidiasis and discomfort.

SIDE EFFECTS
Although central atropine-like side effects such as confusion are thereby reduced due to poor penetration across the blood-brain barrier of Hyoscine-N-butylbromide, peripheral atropine-like side effects remain common with dry mouth, difficult visual accommodation, hesitant micturition, and constipation at doses which act as gut neuromuscular relaxant. The elderly are particular susceptible; glaucoma and urinary retention may occur. Other side effects include flushing, dry skin, bradycardia followed by tachycardia; very rarely fever, confusional states and rashes. When anticholinergics are given to patients, especially children, where the environmental temperature is high, there is risk of a rapid increase in body temperature because of suppression of sweat glan activity.

CONTRAINDICATION
Because of a possible mydriatic effect, Hyomide should not be administered to patients with glaucoma. It is also contraindicated in the following: porphyric patients; refux oesophagitis; gastrointestinal tract obstructive disease as in achalasia and pyloroduodenal stenosis; hernia, hiatal, associated with reflux oesophagitis; paralytic ileus; myasthenia gravis; prostatic hypertrophy; urinary retention; pyloric obstruction, tachycardia; ulcerative colitis, megacolon and it should not be used in patients who have demonstrated prior sensitivity to Hyoscine-N-butylbromide.

DRUG INTERACTIONS
The two main types of drug interactions involves:
1. Because of decreased gastrointestinal motility and delayed gastric emptying, absorption of other oral medications may be decreased during concurrent use with anticholinergics and
2. Many drugs have antimuscarinic effects; concomitant use of two or three such drugs can increase side-effects such as dry mouth, urine retention and constipation.

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance.

Alkalisers (antacid, carbonic anhydrase inhibitors, citrate, sodium bicarbonate): Urinary excretion of anticholinergics such as Hyomide may be delayed by alkalisation of the urine.

Antifungals: Reduced absorption of ketoconazole.

Antihistamines: Increased antimuscarinic side-effects

Cisapride: antagonism of gastro-intestinal effect

Dopaminergics: Increased antimuscarinic side-effects with amantadine.

Metoclopramide and Domperidone: Concurrent use with anticholinergics may antagonise their effects on gastrointestinal motility.

Nitrates: Reduced effect of sublingual nitrates (failure to dissolve under tongue owing to dry mouth)

Opiod (narcotic) analgesics: concurrent use with anticholinergics may increased risk of severe constipation, which may lead to paralytic ileus, and / or urinary retention.

PRECAUTIONS
Although Hyoscine-N-butylbromide has been in wide general use for many years, there is no definite evidence of ill- consequence during human pregnancy. Nevertheless, medicines should not be used in pregnancy, especially the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus. Because of the potential risk of anticholinergic complications, caution should be used in elderly, urinary retention, prostatic enlargement, tachycardia, cardiac insufficiency, paralytic ileus, ulcerative colitis, and pyloric stenosis; may aggravate gastro- oesophageal reflux.

Laboratory Value Alteration
The following has been selected on the basis of their potential clinical significance – not necessarily inclusive:
With diagnostic test results.

For all anticholinergics
Gastric acid secretion test - concurrent use of anticholinergics may antagonize the effect of pentagastrin and histamine in the evaluation of gastric acid secretory function; administration of anticholinergics is not recommended during the 24 hours preceding the test.
Radionuclide gastric emptying studies - use of anticholinergics may result in delayed gastric emptying.

PRESENTATION
Blister Pack: 10 x 10's, 50 x 10's & 100 x 10's

STORAGE CONDITIONS AND USER INSTRUCTIONS
Keep container tightly closed.
Store in a dry place below 30°C.
Protect from light.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

Shelf-life: Please refer to outer package

Route of administration : Oral

Product Registration Holder:
Duopharma Manufacturing (Bangi) Sdn. Bhd.
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Revision date: April 2021

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