

For the use only of a Registered medical practitioner or a hospital or a laboratory.

HYOCE

(Hyoscine Butylbromide Injection BP)

COMPOSITION :

Each ml contains:
Hyoscine Butylbromide BP 20mg
Water for Injections BP q.s.

PHARMACOLOGICAL CLASSIFICATION :
Gastro-intestinal antispasmodics.

PHARMACOLOGICAL ACTION :

Hyoscine butylbromide is a quaternary ammonium anticholinergic agent, the peripheral effects of which are similar to those of atropine, but weaker and of shorter duration.

INDICATIONS :

Hyoscine butylbromide is used in the treatment of conditions associated with gastro-intestinal spasm.

CONTRA-INDICATIONS :

Enlarged prostate. Closed angle glaucoma, or narrow angle between the iris and cornea as hyoscine increases intra-ocular pressure.

WARNING AND PRECAUTIONS:

The safe use of Hyoscine is contentious in patients with porphyria.

Therapy should be discontinued if the patient reports any unusual visual disturbances or pressure pain within the eye.

Patients intolerant of one belladonna alkaloid or derivative may also be intolerant of other belladonna alkaloid or derivatives such as hyoscine butylbromide.

After parenteral administration of hyoscine butylbromide, cases of anaphylaxis, including episodes of shock have been observed. As with all drugs causing such reactions, patients receiving hyoscine butylbromide by injection should be kept under observation.

Hyoscine butylbromide injection should be used with caution in patients with prostatic enlargement. Hyoscine butylbromide may precipitate or aggravate urinary retention in patients with the following conditions: nonobstructive prostatic hypertrophy, urinary retention (or the predisposition to) or obstructive uropathy such as a bladder neck obstruction due to prostatic hypertrophy. In addition, exercise caution in patients inclined to tachyarrhythmia.

Pregnancy and Lactation:

Use of hycoc during pregnancy may cause respiratory depression in the neonate, and should only be given during pregnancy when the potential benefit clearly outweighs the foetal hazard.

Amount of hycoc in breast milk is too small to be harmful.

Special Precautions :

Hyoc should be used with caution in patients with pyloric stenosis, those who have bladder outflow obstruction, or in patients with intestinal obstruction.

Patients should not consume alcohol whilst using Hycoc.

Hyoc should also be used with caution in elderly patients, and in patients with impaired hepatic or renal function.

In rare cases, confusional states and visual hallucinations may occur. In such cases, Hycoc should be removed immediately. If severe symptoms persist, appropriate therapeutic measures should be taken.

Idiosyncratic reactions may occur with ordinary therapeutic doses of hyoscine.

In isolated cases an increase in seizure frequency in epileptic patients has been reported.

Care should be taken after removal of the system as side-effects may persist for up to 24 hours or longer.

Side Effects

Adverse reactions that may be caused by using this drug are usually minor or mild. On the other hand, it may also give rise to many serious adverse reactions. Common side effects caused by it are bloated feeling; constipation; blurred vision; decreased sweating; dilation of pupils; difficulty sleeping; dizziness; dry mouth; drowsiness; headache; nausea; loss of taste; nervousness; urinary retention. If any severe adverse reactions occur, consult the doctor right away. A few such effects are diarrhea, changes in heartbeat, difficulty focusing your eyes; pounding in the chest; difficulty urinating; rapid heart rate; vomiting and unusual weakness.

DRUG INTERACTIONS:

As hyoscine butylbromide can reduce the motility and secretory activity of the gastrointestinal system, the systemic absorption and pharmacologic effects of other oral medications may be delayed.

Drug - Drug Interactions

Table 1 - Established or Potential Drug-Drug Interactions

Hyoscine Butylbromide	Effect	Clinical comment
Tricyclic antidepressants	Can potentiate the anticholinergic effect of parenterally administered hyoscine butylbromide.	
Antihistamines	Can potentiate the anticholinergic effect of parenterally administered hyoscine butylbromide.	
Quinidine	Can potentiate the anticholinergic effect of parenterally administered hyoscine butylbromide.	
Disopyramide	Can potentiate the anticholinergic effect of parenterally administered hyoscine butylbromide.	
Amantadine	Can potentiate the anticholinergic effect of parenterally administered hyoscine butylbromide.	
MAO inhibitors	May result in intensified anticholinergic side effects of hyoscine butylbromide. Also, may block detoxification of anticholinergics thus potentiating their action.	
Anticholinergics	May intensify anticholinergic effects. May increase the severity of potassium chloride induced gastrointestinal lesions.	
Dopamine antagonists such as metoclopramide	May result in diminution of the effects of both drugs on the gastrointestinal tract.	
Beta-adrenergic agents	May enhance tachycardic effects.	
Antacids or adsorbent antidiarrheals	May reduce the absorption of anticholinergics, resulting in decreased therapeutic effectiveness.	Anticholinergics such as hyoscine butylbromide should be given at least one hour before these medications.

Drug-Food Interactions:

Interactions with food have not been established.

DOSAGE AND DIRECTIONS FOR USE:

The usual dose is 20mg IM or IV, 2 to 3 times a day. Infants and children upto 3 years: 5 mg IM or IV, 2 to 3 times a day. Children upto 6 years: 10mg IM or IV, 2 to 3 times a day.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :

Toxic doses cause tachycardia, rapid respiration, hyperpyrexia, and central nervous system stimulation marked by restlessness, confusion, excitement, paranoid and psychotic reactions, hallucinations and delirium, and occasionally seizures or convulsions. A rash may appear on the face or upper trunk. In severe intoxication central stimulation may give way to central nervous system depression, coma, circulatory and respiratory failure, and death. Quaternary ammonium antimuscarinic agents usually have some ganglion-blocking activity so that high doses may cause postural hypotension and impotence, in toxic doses non-depolarising neuromuscular block may be produced. There is considerable variation in susceptibility to the belladonna alkaloids; recovery has occurred after 1 g, whereas deaths have been reported from doses of 100 mg or less for adults and 10 mg for children. Treatment is to empty the stomach by aspiration and lavage or by induction of emesis. The giving of activated charcoal to reduce absorption prior to lavage, has been suggested. Supportive therapy should be given as required.

STORAGE INSTRUCTIONS :

Store below 30°C, protected from light.
Keep out of reach of children.

PRESENTATION :

Ampoule – 20mg / ml . Pack of 10 x 1ml

Manufactured by :



KILITCH DRUGS (INDIA) LTD.
C- 301/2, TTC Indl area, MIDC,
Pawane, Navi Mumbai - 400705, INDIA.

200 mm

220 mm

Size : 220 x 200 mm