1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

HYOSPASMOL SYRUP

COMPOSITION

Each 5 ml of HYOSPASMOL SYRUP contains hyoscine-N-butylbromide 5 mg

Excipients:

Citric acid monohydrate, disodium EDTA, flavour banana (85509/H), glycerol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol solution 70 % (non-crystallising)

Preservatives:

Sodium benzoate 0,1 % *m/v*

Propylene glycol 3,0 % *m/v*

Contains sugar: Sorbitol (70 %) solution 2 g

Contains sweetener: Glycerol 400 mg, saccharin sodium 4 mg

CATEGORY AND CLASS

A 11.2 Gastrointestinal antispasmodics and cholinolytics (anticholinergics)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Hyoscine-N-butylbromide is a competitive antagonist of the actions of acetylcholine and other muscarinic agonists. It is a quaternary ammonium anticholinergic medicine that acts on the parasympathetic ganglia in the walls of the viscera where it exerts an antispasmodic action on the smooth muscle of the gastrointestinal, urinary and biliary tracts.

Pharmacokinetic properties

Gastrointestinal absorption is poor and irregular. The total absorption after an oral dose is about 10 % to 25 %. Hyoscine-N-butylbromide does not readily cross the blood brain barrier to enter the central nervous system (CNS).

INDICATIONS

For the treatment of conditions associated with gastrointestinal spasm.

CONTRAINDICATIONS

HYOSPASMOL SYRUP is contraindicated in patients with:

- A known hypersensitivity to hyoscine-N-butylbromide
- Closed angle glaucoma or patients with a narrow angle between the iris and cornea
- Myasthenia gravis
- Porphyria
- Fever
- Tachycardia
- Megacolon

- Paralytic ileus, pyloric stenosis and other mechanical stenosis/obstruction of the gastrointestinal tract

HYOSPASMOL SYRUP is contraindicated in pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS

- The sedative effect of HYOSPASMOL SYRUP may be enhanced by alcohol or other central nervous system depressants.
- When given to patients, especially children, where the environmental temperature is high, there is a risk of rapid increase in body temperature due to suppression of sweat gland activity.
- Infants with Down's syndrome, and children with spastic paralysis or brain damage may show an increased response to anticholinergics, thus increasing the potential for side effects.
- Geriatric or debilitated patients may respond to usual doses of anticholinergics with excitement, agitation, drowsiness, or confusion.
- Caution is advised in patients with impaired metabolic, liver or kidney function, as adverse central nervous system effects may be more likely in these patients.
- Needs to be used with caution in patients with, or at risk of urinary retention, including those with prostatic enlargement.
- Use with caution in conditions characterised by tachycardia such as thyrotoxicosis, heart failure, and in cardiac surgery, where they may further accelerate heart rate.
- Care is required in patients with acute myocardial infarction, as ischaemia and infarction may be made worse, and in patients with hypertension.

Effects on ability to drive and use machines

The sedative effect of HYOSPASMOL SYRUP may be enhanced by alcohol or other central nervous system depressants.

Excipients

HYOSPASMOL SYRUP contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take HYOSPASMOL SYRUP.

INTERACTIONS

- The effects of HYOSPASMOL SYRUP may be enhanced by the concomitant administration of the other medicines with antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics and tricyclic antidepressants.
- Inhibition of medicine-metabolising enzymes by monoamine oxidase inhibitors may possibly enhance the effects of HYOSPASMOL SYRUP.
- The reduction in gastric motility caused by HYOSPASMOL SYRUP may affect the absorption of other medicines.
- HYOSPASMOL SYRUP and parasympathomimetics may counteract each other's effects.
- Concomitant treatment with dopamine antagonists, e.g. metoclopramide, may enhance the reduction of motility of the gastrointestinal tract caused by HYOSPASMOL SYRUP.
- HYOSPASMOL SYRUP may enhance tachycardia caused by beta adrenergic medicines.

HUMAN REPRODUCTION

The safety of HYOSPASMOL SYRUP in pregnancy and lactation has not been established.

HYOSPASMOL SYRUP is contraindicated in pregnancy and lactation (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

The initial dose must be the lowest recommended for the age group.

Do not exceed the maximum recommended dose for each age group.

Take 30 minutes to 1 hour before meals in order to maximise absorption.

Babies older than 1 month up to 3 months:

2,5 ml (half a medicine measure) three times daily

Infants older than 3 months up to 1 year:

2,5 ml to 5 ml (half to one medicine measure) three times daily

Children older than 1 year up to 3 years:

5 ml to 10 ml (one to two medicine measures) three times daily

Children older than 3 years up to 6 years:

10 ml (two medicine measures) three times daily

Children older than 6 years up to 12 years:

10 ml to 20 ml (two to four medicine measures) three times daily

Children older than 12 years and adults:

20 ml (four medicine measures) four times daily

SIDE EFFECTS

Gastrointestinal disorders

Frequent: Reduction in tone and motility of the gastrointestinal tract leading to constipation

Less frequent: Vomiting may occur occasionally

Eye disorders

Less frequent: Dilatation of the pupils with loss of accommodation and photophobia

Cardiac disorders

Frequency unknown: Transient bradycardia followed by tachycardia, with palpitations and dysrhythmias

Renal and urinary disorders

Less frequent: Difficulty in micturition

Respiratory, thoracic and mediastinal disorders

Frequency unknown: Reduced bronchial secretions

Skin and subcutaneous tissue disorders

Frequent: Flushing and dryness of the skin

Endocrine disorders

Frequent: Dyshidrosis

General disorders

Frequent: Dryness of mouth with difficulty in swallowing and talking, thirst

Frequency unknown: Hypersensitivity reactions, particularly skin reactions

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

In overdosage, the peripheral effects become more pronounced and other symptoms such as hyperthermia, hypertension, increased respiratory rate, and nausea and vomiting may occur. A rash may appear on the face or upper trunk. Toxic doses also cause CNS stimulation marked by restlessness, confusion, excitement, ataxia, incoordination, paranoid and psychotic reactions, hallucinations and delirium, and occasionally seizures. However, in severe intoxication, central stimulation may give way to CNS depression, coma, circulatory and respiratory failure and death.

Treatment

In cases of overdosage, the stomach should be emptied. Activated charcoal has been suggested to reduce absorption. Supportive therapy should be given as required.

IDENTIFICATION

A clear, colourless to slightly yellow liquid with a sweet banana odour.

PRESENTATION

100 ml are packed in a round, amber glass bottle and sealed with a white polypropylene tamper-evident screw cap with an expanded polyethylene liner. The bottle is packed into a cardboard carton together with a leaflet.

100 ml are packed in a round, high-density polyethylene natural bottle and sealed with a white low-density polyethylene snap-on cap. The bottle is packed into a cardboard carton together with a leaflet.

Not all packs are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a well-closed container.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

A39/11.2/0353

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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