1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

HYOSPASMOL (Sugar-coated tablet)

COMPOSITION

Each sugar-coated tablet of HYOSPASMOL contains hyoscine butylbromide 10 mg.

Excipients

Acacia powder, benzoic acid, calcium carbonate, carnauba wax, dye Lennon white no. 101, ethylparabenzoate, kaolin, lactose monohydrate, magnesium stearate, methyl parahydroxybenzoate sodium, povidone K25, propyl hydroxybenzoate, purified talc, starch maize, sodium benzoate, sucrose.

Preservatives

Benzoic acid and benzoates 0,002 % *m/m*

Contains sugar: Sucrose 171,19 mg and lactose monohydrate 70,0 mg

CATEGORY AND CLASS

A 11.2 Gastrointestinal antispasmodics and cholinolytics (anticholinergics)

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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

INDICATIONS

HYOSPASMOL is used in the treatment of conditions associated with gastrointestinal spasm.

CONTRAINDICATIONS

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

WARNINGS AND SPECIAL PRECAUTIONS

Antimuscarinic medicines should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure, and in cardiac surgery, where it may further accelerate the heart-rate. Care is required in patients with acute myocardial infarction as ischaemia and infarction may be made worse.

Porphyria

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

Excipients

HYOSPASMOL contains lactose monohydrate and sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption, sucrose-isomaltase insufficiency or fructose intolerance should not take HYOSPASMOL.

INTERACTIONS

The effects of antimuscarinic medicines may be enhanced by the concomitant administration of other medicines with antimuscarinic properties, such as amantadine, some antihistamines, butyrophenones and phenothiazines, and tricyclic antidepressants. The reduction in gastric motility caused by antimuscarinic medicines may affect the absorption of other medicines.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Adult dose:

20 mg four times daily.

Paediatric dose:

Children 1 to 3 years: 5 mg to 10 mg three times daily.

Children 3 to 6 years: 10 mg three times daily.

*Children 6 to 12 years:*10 mg to 20 mg three times daily.

SIDE EFFECTS

Dryness of the mouth, with difficulty in swallowing and talking, thirst, dilatation of the pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia, flushing and dryness of the skin, transient bradycardia followed by tachycardia, with palpitations and dysrhythmias, and urinary urgency, difficulty and retention, as well as reduction in the tone and motility of the gastrointestinal tract leading to constipation. Occasionally vomiting, giddiness and staggering may occur. Retrosternal pain may occur due to increased gastric reflux.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

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 medicines 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

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.

IDENTIFICATION

A white, round biconvex sugar-coated tablet.

PRESENTATION

10 or 20 tablets are packed in a white polypropylene securitainer and sealed with a yellow low-density polyethylene cap together with or without foam insert or rayon and a leaflet.

10 or 20 tablets are packed in a polyvinyl chloride / polyvinylidene chloride blister strip sealed with an aluminium foil backing. The blister strip is packed into an outer cardboard carton together with a leaflet.

10 or 20 tablets are packed in a metallised polyester laminated with opaque linear low-density polyethylene layflat and sealed with a low-density polyethylene Ziploc seal.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/11.2/59

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

PHARMACARE LIMITED

Healthcare Park

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

Date of registration: 20 July 1979

Date of the most recent amendment to the professional information as approved by the Authority: 06 January 1993

Botswana: BOT0901531 S2

Namibia: NS1 90/11.2/00975

Zimbabwe: P.I.M. 91/16.4/2563

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