1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

LAXADOR BISACODYL (film-coated tablet)

COMPOSITION

Each film-coated tablet of LAXADOR BISACODYL contains 5 mg bisacodyl.

Excipients:

Antifoam M30, colloidal anhydrous silica, gelatin, hypromellose, iron oxide red (C.I. 77491), lactose monohydrate, magnesium stearate, maize starch, methacrylic acid copolymer, ponceau 4R aluminium lake (C.I. 16255), purified talc, sodium bicarbonate, sodium lauryl sulphate, titanium dioxide (C.I. 77891), triacetin, triethyl citrate

Contains sugar: Lactose monohydrate 40 mg

CATEGORY AND CLASS

A 11.5 Medicines acting on the gastrointestinal tract: Laxatives

PHARMACOLOGICAL ACTION

Promotes bowel movement by one or more direct actions on the intestine.

INDICATIONS

LAXADOR BISACODYL is indicated for the treatment of occasional constipation.

CONTRAINDICATIONS

Hypersensitivity to the ingredients.

Intestinal obstruction or with undiagnosed abdominal symptoms.

WARNINGS AND SPECIAL PRECAUTIONS

This medicine should not be used in the presence of abdominal pain, nausea or vomiting.

Frequent or prolonged use of LAXADOR BISACODYL may result in dependence on laxatives and loss of normal bowel function. If you have noticed a sudden change in bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using the laxative.

The use of any laxative beyond 1 week is not recommended except on the advice of a doctor. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a doctor.

Care should be taken in patients with inflammatory bowel disease.

Excipients

LAXADOR BISACODYL contains lactose 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 or fructose intolerance should not take LAXADOR BISACODYL.

INTERACTIONS

Do not take LAXADOR BISACODYL within one hour after taking an antacid or milk (see

DOSAGE AND DIRECTIONS FOR USE).

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

LAXADOR BISACODYL generally produces bowel movement in 6 to 12 hours.

Do not chew the tablets.

Do not give to children under 6 years of age or to persons who cannot swallow without chewing unless directed by a doctor.

Do not take this product within one hour after taking an antacid or milk.

Adults and children 12 years and over:

One to three tablets in a single daily dose.

Children 6 to under 12 years:

One tablet in a single daily dose.

SIDE EFFECTS

May cause abdominal discomfort, diarrhoea, colic and cramps.

Prolonged use may lead to diarrhoea with excessive loss of water and electrolytes and possible atonic non-functioning colon.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

See SIDE EFFECTS.

Treatment is symptomatic and supportive.

IDENTIFICATION

A reddish-brown, enteric film-coated, round, biconvex tablet, plain on both sides.

PRESENTATION

30 tablets are packed in a white, cylindrical, polypropylene container sealed with a yellow medium density polyethylene screw cap together with a foam insert and a leaflet.

200 tablets are packed in a white, cylindrical polypropylene container sealed with a white low density polyethylene cap together with a foam insert and a leaflet.

10 tablets are packed in a clear polyvinylchloride or polyvinylchloride, polyvinylidene film sealed with a silver, aluminium foil backing. The strip is placed in an outer cardboard carton together with a leaflet.

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

E/11.5/1558

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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