1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

BROOKLAX BISACODYL LAXATIVE PILLS (enteric-coated tablet)

COMPOSITION

Each enteric-coated tablet of BROOKLAX BISACODYL LAXATIVE PILLS contains 5 mg of bisacodyl.

Excipients

Black iron oxide (C.I. 77499), carnauba wax, co-processed polyvinyl acetate, colloidal anhydrous silica, croscarmellose sodium, dextrose monohydrate, hypromellose, iron oxide red (C.I. 77491), lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised maize starch, purified stearic acid, sodium alginate, sodium bicarbonate, talc, titanium dioxide (C.I. 77891), triethyl citrate.

Contains sugar: Lactose monohydrate 2,029 g, dextrose monohydrate 16,0 mg

CATEGORY AND CLASS

A 11.5 Laxatives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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

INDICATIONS

BROOKLAX BISACODYL LAXATIVE PILLS are recommended for relief of occasional constipation.

CONTRAINDICATIONS

- Sensitivity to the ingredients.
- Intestinal obstruction.
- Undiagnosed abdominal symptoms, or acute surgical abdominal conditions such as acute appendicitis, acute inflammatory bowel disease.
- Severe dehydration.
- Safety in pregnancy and lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

- BROOKLAX BISACODYL LAXATIVE PILLS should not be used in the presence of abdominal pain, nausea or vomiting.
- Do not use for a period longer than one week except on the advice of a doctor.
- If you have noticed a sudden change in bowel habits that has persisted for a period of longer than 2 weeks, consult a doctor before using BROOKLAX BISACODYL LAXATIVE PILLS.
- 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.
- Frequent or prolonged use of BROOKLAX BISACODYL LAXATIVE PILLS may result in dependence on laxatives and loss of normal bowel function.
- Do not chew these tablets.

- Children should not take BROOKLAX BISACODYL LAXATIVE PILLS without medical advice. Do not give to children under the age of 6 years or to persons who cannot swallow them without chewing unless directed by a doctor.
- Do not take BROOKLAX BISACODYL LAXATIVE PILLS within one hour after taking an antacid or milk.
- If a laxative is needed every day, the cause of constipation should be investigated.
- Care should be taken in patients with inflammatory bowel disease.
- Prolonged use may lead to diarrhoea with excessive loss of water and electrolytes, particularly potassium, and possible atonic non-functioning colon.

Excipients

BROOKLAX BISACODYL LAXATIVE PILLS contains dextrose and 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 BROOKLAX BISACODYL LAXATIVE PILLS.

INTERACTIONS

The concomitant use of diuretics or adreno-corticoids may increase the risk of electrolyte imbalance if excessive doses of BROOKLAX BISACODYL LAXATIVE PILLS are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Bowel movement will generally occur in 6 to 12 hours.

Do not chew.

The tablets should be swallowed whole with adequate fluid.

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

Do not take BROOKLAX BISACODYL LAXATIVE PILLS within one hour after taking an antacid or milk.

The tablets should be taken at night to produce evacuation the following morning.

Adults and children over 12 years:

Take one to three tablets daily in a single dose.

Children 6 to 12 years:

Take one tablet daily.

Not for use in children under six years.

SIDE EFFECTS

May cause abdominal discomfort, diarrhoea, colic, and cramps.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

See SIDE EFFECTS.

Treatment

Treatment is symptomatic and supportive.

Absorption can be minimised or prevented by inducing vomiting or gastric lavage.

Replacements of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young.

IDENTIFICATION

A chocolate coloured, round, biconvex, flat edge, enteric-coated tablet.

PRESENTATION

10 tablets are packed in a clear polyvinylchloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton.

10 tablets are packed in a clear polyvinylchloride and polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton.

Not all packs are necessarily marketed.

STORAGE INSTRUCTIONS

Keep at or below 25 °C, in a cool dry place.

Keep tablets in the blister pack.

Do not remove the blister from the carton until required for use.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

36/11.5/0104

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

PHARMACARE LIMITED

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Woodmead 2191

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

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