SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **FRESHEN BISACODYL LAXATIVE**

(AND DOSAGE FORM) **(TABLET)**

COMPOSITION:

Each tablet contains:

Bisacodyl 5 mg

Contains sugar: Lactose 134,24 mg

List of excipients: Gelatin, magnesium stearate, maize starch, pregelatinised starch, purified water, lactose,Opadry II white 85F 18422, Acryl –Eze green 93021456, simethicone emulsion

Contains sugar: Lactose

PHARMACOLOGICAL CLASSIFICATION:

A: 11.5 Laxatives

PHARMACOLOGICAL ACTION:

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

INDICATIONS:

For the relief of occasional constipation.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

Undiagnosed abdominal symptoms, for example pains, or patients with symptoms of intestinal obstruction.

Safety in pregnancy and lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:

- This medicine should not be used in the presence of abdominal pain, nausea or vomiting.
- **FRESHEN BISACODYL LAXATIVE** should not be used for a period longer than one week, unless directed by a doctor.
- If you have noticed a sudden change in bowel habits that has persisted for a period longer than 2 weeks, consult a doctor before using the laxative.
- 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 this preparation may result in dependence on laxatives and loss of normal bowel function.
- Care should be taken in patients with inflammatory bowel disease.
- **FRESHEN BISACODYL LAXATIVE** contains lactose. Patients with rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption should not take FRESHEN BISACODYL LAXATIVE.
- **FRESHEN BISACODYL LAXATIVE** contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

This product generally produces bowel movements in 6 to 12 hours.

Adults and children over 12 years of age: 1 to 3 tablets in a single daily dose.

Children 6 to under 12 years: One table in a single daily dose.

Not recommended for use in children under the age of 6 years.

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

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

DO NOT CHEW THE TABLETS.

SIDE EFFECTS

May cause abdominal discomfort such as diarrhoea, colic and cramps. Prolonged use or overdosage may result in diarrhoea, excessive loss of water and electrolytes and possible atonic non-functioning colon.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "**SIDE EFFECTS AND SPECIAL PRECAUTIONS**".

Treatment is symptomatic and supportive.

IDENTIFICATION:

Light green, round, enteric film-coated tablets.

PRESENTATION:

2's or 3's in polypaper sachets; 2 polypaper sachets containing 2 tablets each packed in a carton, 12's, 30's in Alu/clear PVC blisters, 24's, 30's and 200's in white PP securitainers; 200's in amber glass bottles and 1 000's in amber HDPE bottles.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in airtight containers, protected from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/11.5/1668

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

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