SCHEDULING STATUS:

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

PURITONE BISACODYL LAXATIVE (FILM COATED TABLET)

Read all of this leaflet carefully because it contains important information for you.

PURITONE BISACODYL LAXATIVE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use PURITONE BISACODYL LAXATIVE

carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PURITONE BISACODYL LAXATIVE with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

WHAT PURITONE BISACODYL LAXATIVE CONTAINS

The active substance in each film-coated tablet is 5 mg of Bisacodyl.

Contains sugar: Lactose 0,1324 g

The other ingredients are: acryl –eze brown 93026763, gelatin, magnesium stearate, maize starch, opadry II white 85F 18422, pregelatinised starch, purified water, simethicone emulsion

WHAT PURITONE BISACODYL LAXATIVE IS USED FOR:

Bisacodyl belongs to a group of medicines known as stimulant laxatives. Stimulant laxatives increase bowel movements.

PURITONE BISACODYL LAXATIVE Tablets are used for recent or long term constipation.

BEFORE YOU TAKE PURITONE BISACODYL LAXATIVE

Do not take PURITONE BISACODYL LAXATIVE tablets:

- If you are hypersensitive (allergic) to ebastine or any of the other ingredients in **PURITONE BISACODYL LAXATIVE**.
- If you have **severe abdominal pain** with nausea and vomiting
- If you have a **blocked bowel** (intestinal obstruction)
- If you have **inflammation of the bowel** (small or large intestine)
- If you have 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
- **PURITONE BISACODYL LAXATIVE** must not be given 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
- If you are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**).

Take special care with PURITONE BISACODYL LAXATIVE:

- If you have **severe abdominal pain** with nausea and vomiting
- If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.
- **PURITONE 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.
- Discontinue use and consult a doctor.
- When intended for bowel cleansing, do not use this product unless directed by a doctor.

- Prolonged use or over-dosage may result in diarrhoea, excessive loss of water and electrolytes and possible atonic non-functioning colon.
- Care should be taken in patients with inflammatory bowel disease.

Taking PURITONE BISACODYL LAXATIVE with food and drink:

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

Pregnancy and Breastfeeding:

Safety in pregnancy and lactation has not been established.

If you are pregnant or breastfeeding while taking PURITONE BISACODYL LAXATIVE please consult your doctor, pharmacist or other health care professional for advice

Important information about some of the ingredients of PURITONE BISACODYL LAXATIVE:

PURITONE BISACODYL LAXATIVE Tablets contain lactose:

If a doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine

Taking other medicines with PURITONE BISACODYL LAXATIVE:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

HOW TO TAKE PURITONE BISACODYL LAXATIVE

Do not share medicines prescribed for you with any other person.

Always take PURITONE BISACODYL LAXATIVE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

How to take PURITONE BISACODYL LAXATIVE:

- **PURITONE BISACODYL LAXATIVE** must be taken orally i.e. by mouth.
- **PURITONE BISACODYL LAXATIVE** must be swallowed with a glass of water.
- **PURITONE BISACODYL LAXATIVE** can be taken with or without food.
- Take **PURITONE BISACODYL LAXATIVE** once a day, at about the same time each day.

The usual dose is:

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

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

PURITONE BISACODYL LAXATIVE must not be given 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

If you take more PURITONE BISACODYL LAXATIVE than you should:

In the event of overdosage of PURITONE BISACODYL LAXATIVE, consult your doctor or pharmacist. If neither is available, contact **at the nearest hospital or poison control centre.**

POSSIBLE SIDE EFFECTS :

These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

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

Not all side-effects reported for **PURITONE BISACODYL LAXATIVE** are included in this leaflet.

Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF PURITONE BISACODYL LAXATIVE:

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date shown on the container

PRESENTATION OF PURITONE BISACODYL LAXATIVE:

2's or 3's - 72x2's or 72x3's and 48x2's or 48x3's in polypaper sachets, 12's and 20'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

IDENTIFICATION OF PURITONE BISACODYL LAXATIVE:

Light brown, round, enteric film-coated tablets.

REGISTRATION NUMBER:

E/11.5/983

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF APPLICANT:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

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