

## **PRODUCT INFORMATION**

### **BISALAX<sup>®</sup> (bisacodyl)**

#### **NAME OF THE DRUG:**

Bisacodyl.

#### **DESCRIPTION:**

Bisacodyl is a white or almost white crystalline powder; odourless, or almost odourless; and tasteless. Chemically, bisacodyl is 4,4'-(2-pyridylmethylene)di(phenylacetate). Its molecular weight is 361.38.

Bisalax tablets contain 5 mg bisacodyl. Core excipients include lactose, starch maize, macrogol 6000, glycerol, gelatin, magnesium stearate and silica colloidal anhydrous. The enteric coating excipients include hypromellose, propylene glycol, hypromellose phthalate, diethyl phthalate and quinoline yellow CI 47005.

Bisalax enema contains 10 mg bisacodyl/5 mL tube. Excipients include citric acid monohydrate, macrogol 3000, macrogol 400, macrogol 4000 and sodium citrate.

#### **ACTIONS:**

Bisacodyl is a contact laxative. Its action is restricted mainly to the colon; the motility of the small intestine is not appreciably influenced. Bisacodyl acts locally in the gastrointestinal tract, stimulating sensory nerve endings in the colonic mucosa to produce parasympathetic reflexes resulting in increased peristaltic contractions of the colon. Local axon reflexes as well as segmental reflexes are initiated in the region of contact and contribute to the widespread peristaltic activity producing evacuation. For this reason, bisacodyl may be employed satisfactorily in patients with ganglionic blockage or spinal cord damage (paraplegia, poliomyelitis etc).

#### **PHARMACOLOGY:**

The precise mode of action is unknown. Although previously thought not to be absorbed from the digestive tract, recent studies have shown that up to 5% of an oral dose of bisacodyl may be absorbed in man. Bisacodyl is excreted mainly in faeces, and partly in urine as the glucuronide. When taken on an empty stomach, bisacodyl tablets will exert their effect in 6 to 8 hours. When taken with food, the effect of the tablets will occur in 10 to 12 hours.

#### **INDICATIONS:**

Constipation due to confinement to bed, unaccustomed diet or change of environment. Constipation in cases of serious diseases, circulatory disturbances and metabolic disorders; occasional use in chronic constipation; bowel re-training; postoperatively in cases of haemorrhoids and anal fissures; colostomies; preparation for radiography; preparation for sigmoidoscopy or proctoscopy; preoperative preparation; postoperative care; antepartum and postpartum constipation; and preparation for delivery.

#### **CONTRAINDICATIONS:**

Bisacodyl has the same contraindications as other laxatives.

All laxatives are contraindicated in patients with cramps, colic, nausea, vomiting or other symptoms as in appendicitis, inflammatory bowel disease, acute abdominal situations such as ileus, intestinal obstruction or any other undiagnosed abdominal pain.

Bisalax is also contraindicated in dehydration, hypokalaemia, hypersensitivity to bisacodyl or to any of the excipients.

Bisalax enemas are contraindicated in patients with anal fissure, ulcerative proctitis with mucosal damage and ulcerated haemorrhoids.

## **PRECAUTIONS:**

### Warnings

Prolonged use of laxatives may lead to dependence, chronic constipation and loss of bowel function. "Cathartic colon" with atony, dilatation and resemblance of ulcerative colitis or proctitis, is also possible.

In addition, continued use of irritant laxatives may produce serious loss of electrolytes, especially potassium and result in disturbances of cardiac function, diarrhoea, dehydration, malabsorption and protein losing enteropathy.

Syncope has been reported during the use of Bisalax. The event could be related to defecation syncope or to a vasovagal response to abdominal pain.

As each Bisalax tablet contains 57.3 mg lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

### Interactions

Milk products and antacids should not be given within one hour of administering Bisalax tablets.

Concomitant use of diuretics or systemic corticosteroids may increase the risk of electrolyte imbalance. This interaction is significant only if excessive doses of Bisalax are taken.

By increasing the motility of the small intestine and speeding the passage, Bisalax can alter the bioavailability of some drugs absorbed mainly from the small intestine such as digoxin and controlled release formulations.

### Use in pregnancy

Category A of Australian Categorisation of Risk of Drug Use in Pregnancy.

### Use in Lactation

There is no contraindication to use of Bisalax by nursing mothers, however as bisacodyl is excreted in the breast milk in low quantities, the drug should only be used during lactation when clearly indicated.

### Use in children

Children should not make frequent use of Bisalax unless medically supervised.

Bisalax tablets: Not recommended for use in children under 6 years of age.

## **ADVERSE REACTIONS:**

Bisacodyl is well tolerated and side effects are rare. However, side effects in the form of diarrhoea, local rectal irritation, proctitis, slight indisposition, epigastralgia, tenesmus, nausea, abdominal pain and cramping have been reported. A possible colic should be treated with atropine derivatives.

Rare cases of vomiting, mild transient skin reactions and hypersensitivity reactions including angioedema and anaphylactoid reactions have also been described.

## **DOSAGE & ADMINISTRATION:**

The enemas can be used in conjunction with tablets. Taken at bedtime, Bisalax tablets are almost invariably effective by the following morning. When taken before breakfast, they usually produce an effect within 6-8 hours. The effects of the enema occur normally within 5 to 15 minutes.

### **Adults**

Preparation for X-ray examination of abdominal organs: The day prior to the examination, 2 tablets are taken orally at lunchtime and 2 tablets in the evening. One enema is inserted into the rectum in the morning one to two hours prior to examination. No food should be given following the administration of the tablets to prevent re-accumulation of material in the caecum.

After X-ray examination: To treat constipation due to barium contrast medium, use one enema.

Acute Constipation: Initially one enema, then 1 or 2 tablets late in the evening and 1 enema in the morning (after breakfast) for about three days.

Constipation in elderly patients: One enema in the morning (after breakfast) on days in which defecation is desired.

Chronic constipation and bowel retraining: By gradually increasing the interval between doses as colonic tone improves, the drug has been found to be effective in redeveloping proper bowel hygiene. There is no tendency to "rebound".

Antepartum Use: One enema immediately before delivery is anticipated.

Postpartum or postoperative constipation: One enema to be used immediately after breakfast for two or three days.

Preparation for sigmoidoscopy proctoscopy: For sigmoidoscopy scheduled in advance, administration of tablets the night before and one enema rectally one hour before the examination will almost invariably result in adequate preparation.

Preparation for surgery of the colon. Two tablets at lunchtime and two tablets in the evening on the day before the operation. One enema should be inserted into the rectum on the morning of surgery.

Colostomies: Two tablets the night before inserted into the colostomy opening in the morning will frequently make irrigations unnecessary and in other cases will expedite the procedure.

### **Children**

Bisalax tablets: Not recommended for use in children under 6 years of age.

Preparation for X-ray examination of abdominal organs:

**Under 1 year:** half an enema the night before the examination and half an enema in the morning on the day of the examination.

**1 to 3 years:** One enema the night before the examination and one enema in the morning of the day of the examination.

**3 to 6 years:** One enema in the afternoon of the day before the examination and one enema in the morning of the day of the examination.

**6 to 12 years:** One tablet at 10am and one enema in the afternoon of the day before the examination.

**Over 12 years:** Two tablets at 10am and two tablets in the evening of the day before the examination and one enema on the morning of the day of the examination.

Constipation:

**Under 3 years:** half an enema (Note. Only half the point of the tube should be inserted).

**3 to 6 years:** One enema as required.

**6 to 12 years:** One tablet in the evening, and one enema in the morning.

Advice to Patients:

If you have noticed a persistent change in bowel habits, consult a physician before using a laxative.

Laxative products should not be used longer than one week unless directed by a physician (see Precautions).

Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult a physician.

Do not crush or chew Bisalax tablets. Swallow Bisalax tablets whole. Do not take milk products or antacids within one hour of taking Bisalax tablets.

Bisalax enemas should be administered rectally when required (see DOSAGE & ADMINISTRATION). Pull off plastic cap from end of nozzle, insert nozzle in rectum and squeeze tube to administer contents. The nozzle of the Bisalax enema may be coated with a lubricant to aid insertion.

**OVERDOSAGE:**

Contact the Poisons Information Centre on 131126 for advice.

**PRESENTATION AND STORAGE CONDITIONS:**

**5 mg tablets:**

Yellow, round, convex enteric coated tablet with no scoring. Available in bottles of 200 tablets or blister packs of 50 tablets\*.

Store BISALAX tablets in the original packaging, at a temperature below 25°C and away from direct light and moisture.

**10 mg/5 mL enemas:**

Yellow tube with yellow flip off cap which contains a white to grey viscous material. Available in packs of 25 enemas.

(\* blister packs of 50 tablets currently not marketed in Australia)

Store BISALAX enemas in the original packaging at a temperature at 2°C to 8°C. (Refrigerate. Do not freeze). Before use, allow the enema to reach room temperature.

**POISON SCHEDULES:**

Unscheduled.

**NAME AND ADDRESS OF THE SPONSOR:**

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AUSTRALIA

**DATE OF TGA APPROVAL:**

Approved by the Therapeutic Goods Administration: 10 August 1999  
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