

PACKAGE INSERT

LAXODYL TABLET 5MG

Each tablet contains:
Bisacodyl 5mg

Product Description: Round, egg yellow, enteric and sugar-coated tablet with no markings or embossment.

Pharmacodynamics:

Bisacodyl is a contact laxative acting directly on the colonic mucosa to produce normal peristalsis throughout the large intestine. The contact action of the drug is restricted to the colon, and motility of the small intestine is not appreciably influenced. Local axon reflexes as well as segmental reflexes are initiated in the region of contact and contribute to the widespread peristaltic activity producing evacuation.

Pharmacokinetics:

Administered orally, bisacodyl is absorbed to a variable degree from the small bowel but such absorption is not related to the mode of action of the compound. Whatever amount of bisacodyl absorbed is excreted in the urine as glucuronide. About 3% of the glucuronide appears in the bile after 10 hours. Bisacodyl is hydrolysed to bis(p-hydroxyphenyl) pyridyl-2-methane which is responsible for its laxative action. It acts within 10 to 12 hours when given after food. Bisacodyl is mainly excreted in the faeces.

Indication:

It is indicated in the treatment of acute and chronic constipation, for bowel retraining, for evacuation of the colon before radiological examination of the abdomen, or endoscopy, and before or after surgical operations.

Recommended Dosage:

For adults only : 5 to 10mg daily.

Up to 6 tablets may be safely given in preparation for special procedures when greater assurance of complete evacuation of the colon is desired. The tablets should be taken at night to produce evacuation the following morning. They should be swallowed whole with adequate fluid.

Route of Administration: Oral

Contraindications:

It is contraindicated in patients who have demonstrated hypersensitivity to it and in an acute surgical abdomen.

Warnings and Precautions:

It should not be taken by patients with intestinal obstruction, abdominal pain, nausea or vomiting. The tablets are enteric-coated and must be swallowed whole, not chewed or crushed and should not be taken within one hour of antacids or milk. Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia and may precipitate onset of rebound constipation.

Interactions with Other Medicaments:

The concomitant use of diuretics or adrenocorticosteroids may increase the risk of electrolyte imbalance if excessive doses of bisacodyl are taken. Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

Pregnancy and Lactation:

Long experience has shown no evidence of undesirable or damaging effects during pregnancy. Nevertheless, as with all drugs, bisacodyl should only be taken during pregnancy on medical advice. Whether bisacodyl passes into breast milk has not been established. Breastfeeding during bisacodyl treatment is therefore not recommended.

Side Effects:

Severe abdominal cramps and excessive purgation and fixed eruption have been observed.

Symptoms and Treatment of Overdose:

Severe abdominal cramps and excessive purgation may occur. Excessive purgation may produce watery diarrhoea with excessive loss of water and electrolytes particularly. Gastric lavage is recommended. Electrolyte balance should be monitored and maintained.

Storage Conditions: Store at or below 30°C. Protect from light.

Pack Size: Blister Pack: A box of 10x10, 50x10 and 100x10 tablets per strip.

Pack Size (export only): A bottle of 1000 tablets.

Shelf-life: 5 years.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM
YOUR FAMILY PHYSICIAN/LOCAL GENERAL PRACTITIONER/PHARMACIST.

Manufacturer & Product Registration Holder:

SUNWARD PHARMACEUTICAL SDN. BHD.

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TL638A-R8
Revision Date: 23/01/2026