



## Composition

1 coated tablet contains 5 mg  
1 suppository contains 10 mg  
1 paediatric suppository contains 5 mg  
4,4'-diacetoxy-diphenyl-(pyridyl-2)-methane  
(= bisacodyl)

## Excipients:

tablets: lactose, maize starch, glycerol,  
magnesium stearate, saccharose, talc, acacia,  
titanium dioxide, eudragit L100 and S100,  
dibutylphthalate, polyethylene glycol, iron oxide  
yellow, beeswax white, carnauba wax, shellac

suppositories: witepsol E76, witepsol E45

## Pharmacological Properties

Bisacodyl is a locally acting laxative from the diphenylmethane derivatives group. As an antiresorptive hydragogue laxative (stimulant laxative) DULCOLAX stimulates, after hydrolysis in the large intestine, peristalsis of the colon and promotes accumulation of water and electrolytes in the colonic lumen.

## Indications/Usage

For use in patients suffering from constipation. In preparation for diagnostic procedures, in pre- and postoperative treatment and in conditions, which require defecation to be facilitated, DULCOLAX should be used under medical supervision.

## Contraindications

DULCOLAX is contraindicated in patients with ileus, intestinal obstruction, acute surgical abdominal conditions including appendicitis, acute inflammatory bowel diseases, and in severe dehydration. It is also contraindicated in patients with known hypersensitivity to bisacodyl or any other component of the product.

## Special warnings and precautions

As with all laxatives, DULCOLAX should not be taken on a continuous daily basis for long periods. If laxatives are needed every day, the cause of constipation should be investigated. Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia, and may precipitate onset of rebound constipation. Dizziness and/or syncope have been reported in

The tablets should be taken at night to produce evacuation the following morning. They should be swallowed whole with adequate fluid. The tablets should not be taken together with milk or antacids.

## Suppositories

Adults and children over 10 years:

1 suppository (10 mg)

Children under 10 years:

1 paediatric suppository (5 mg)

Suppositories are usually effective in about 30 minutes.

They should be unwrapped and inserted into the rectum pointed end first.

## For preparation for diagnostic procedures and preoperatively.

When using DULCOLAX to prepare the patient for radiographic examination of the abdomen or preoperatively, tablets should be combined with the suppositories in order to achieve complete evacuation of the intestine.

The dosage recommended for adults is two to four tablets the night before and one suppository to be inserted the following morning. In the case of children 4 years of age and over, one tablet in the evening and one paediatric suppository on the following morning is recommended.

## Overdose

### Symptoms

If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of potassium and other electrolytes can occur. Chronic overdose with DULCOLAX may cause chronic diarrhoea, abdominal pain, hypokalaemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalaemia have also been described in association with chronic laxative abuse.

## Therapy

After ingestion of oral forms of DULCOLAX, absorption can be minimised or prevented by inducing vomiting or gastric lavage. Replacement

Dizziness and/or syncope have been reported in patients who have taken DULCOLAX. The details available for these cases suggest that the events would be consistent with defecation syncope (or syncope attributable to straining at stool), or with a vasovagal response to abdominal pain which may be related to the constipation that prompted the patients in question to resort to the use of laxatives and not necessarily to the administration of DULCOLAX itself.

The use of suppositories may lead to painful sensations and local irritation, especially in anal fissure and ulcerative proctitis.

Children should not take DULCOLAX without medical advice.

### Interactions

The concomitant use of diuretics or adrenocorticosteroids may increase the risk of electrolyte imbalance if excessive doses of DULCOLAX 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, DULCOLAX should only be taken during pregnancy on medical advice.

Whether bisacodyl passes into breast milk has not been established. Breast feeding during DULCOLAX treatment is therefore not recommended.

### Side Effects

While using DULCOLAX, episodes of abdominal discomfort including cramps and abdominal pain may occur. Diarrhoea has been observed.

Allergic reactions, including isolated cases of angio-oedema and anaphylactoid reactions have been reported in association with the administration of DULCOLAX.

### Dosage and Administration/ Recommended Intake

Unless otherwise prescribed by the physician, the following dosages are recommended:

#### For constipation

##### Coated tablets

Adults and children over 10 years:

1–2 coated tablets (5–10 mg)

Children 4–10 years:

1 tablet (5 mg)

Children under 4 years:

paediatric suppositories are recommended

inducing vomiting or gastric lavage. Replacement of fluids and correction of electrolyte imbalance may be required. This is especially important in the elderly and the young.

Administration of antispasmodics may be of value.

### Availability

Coated tablets of 5 mg

Suppositories of 10 mg

Paediatric suppositories of 5 mg

### Storage instructions

Store below 30 °C. Store in a safe place and out of reach of children. Do not take the medicine after the expiry date printed on the pack.

**Date of package insert:** March 2000

### Manufactured by

**Boehringer Ingelheim France**  
for

**Boehringer Ingelheim International GmbH**  
**Ingelheim am Rhein**  
**Germany**

### This is a medicament

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

The doctors and the pharmacist are experts in medicine, its benefits and risks.

Do not by yourself interrupt the period of treatment prescribed for you.

Do not repeat the same prescription without consulting your doctor.

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**Keep medicament out of reach of children!**

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Council of Arab Health Ministers –  
Union of Arab Pharmacists