

# New Zealand Datasheet

## Name of Medicine

DULCOLAX®

Bisacodyl

## Presentation

Suppository (paediatric): 5mg and Suppository: 10mg, foil wrapped and carry the name DULCOLAX.

Tablet: 5mg: yellow coated tablet.

## Uses

### Actions

Bisacodyl, the active ingredient of DULCOLAX, is a locally acting laxative from the diphenylmethane derivatives group. As a contact laxative, for which also antiresorptive hydragogue laxative effects have been described DULCOLAX stimulates, after hydrolysis in the large intestine, peristalsis of the colon and promotes accumulation of water and consequently electrolytes in the colonic lumen. This results in a stimulation of defecation, reduction of transit time and softening of the stool.

### Pharmacokinetics

Following either oral or rectal administration bisacodyl is rapidly hydrolyzed to the active principle bis-(p-hydroxyphenyl)-pyridyl-2-methane (BHPM), mainly by esterases of the enteric mucosa

Administration as an enteric coated tablet was found to result in maximum BHPM plasma concentrations between 4 - 10 hours post administration whereas the laxative effect occurred between 6 - 12 hours post administration. In contrast, following the administration as a suppository, the laxative effect occurred on average approximately 20 minutes post administration; in some cases it occurred 45 minutes after administration. The maximum BHPM-plasma concentrations were achieved 0.5 - 3 hours following the administration as a suppository. Hence, the laxative effect of bisacodyl does not correlate with the plasma level of BHPM. Instead, BHPM acts locally in the lower part of the intestine and there is no relationship between the laxative effect and plasma levels of the active moiety. For this reason, bisacodyl coated tablets are formulated to be resistant to gastric and small intestinal juice. This results in a main release of the drug in the colon, which is the desired site of action.

After oral and rectal administration, only small amounts of the drug are absorbed and are almost completely conjugated in the intestinal wall and the liver to form the inactive BHPM glucuronide. The plasma elimination half-life of BHPM glucuronide was estimated to be approximately 16.5 hours. Following the administration of bisacodyl coated tablets, an average of 51.8% of the dose was recovered in the faeces as free BHPM and an average of 10.5% of the dose was recovered in the urine as BHPM glucuronide. Following the administration as a suppository, an average of 3.1% of the dose was recovered as BHPM glucuronide in the urine. Stool contained large amounts of BHPM (90% of the total excretion) in addition to small amounts of unchanged bisacodyl.

### Indications

For the use in cases of constipation.

In preparation for diagnostic procedures, in pre- and postoperative treatment and in conditions which require defecation, the use of DULCOLAX must be under medical supervision.

## Dosage and Administration

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

### *Tablets*

**Adults and children over 10 years:** 1 to 2 coated tablets at night (5 to 10mg)

**Children 4 to 10 years:** One tablet at night (5mg).

*Notes:* DULCOLAX tablets are coated. The tablets should be taken at night to produce evacuation the following morning. They should be swallowed whole with adequate fluid.

The coated tablets should not be taken together with products reducing the acidity of the upper gastrointestinal tract, such as milk, antacids or certain proton pump inhibitors, in order not to prematurely dissolve the enteric coating.

### *Suppositories*

**Adults and children over 10 years:** One suppository (10mg)

**Children under 10 years:** One paediatric suppository (5mg)

Do not coat the suppository in any lubricant such as paraffin oil or paraffin jelly. By warming the suppository in the hand before it is removed from the foil wrapper, sufficient lubrication will be produced. Insert into the rectum the pointed end first. Suppositories are usually effective in about 20 minutes (range 10 to 30 minutes).

Children aged 10 years or younger with chronic or persistent constipation should only be treated under the guidance of a physician.

## Contraindications

DULCOLAX should not be used by patients with ileus, intestinal obstruction, acute surgical abdominal conditions including appendicitis, acute inflammatory bowel diseases, and severe abdominal pain associated with nausea and vomiting which may be indicative of more severe conditions.

DULCOLAX is also contraindicated in severe dehydration and in patients with known hypersensitivity to bisacodyl or any other component of the product.

In case of rare hereditary conditions that may be incompatible with an excipient of the product (refer to "Warnings and Precautions") the use of the product is contraindicated.

## Warnings and Precautions

As with all laxatives, DULCOLAX should not be taken on a continuous daily basis for extended periods without investigating the cause of constipation.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and oliguria. In patients suffering from fluid loss where dehydration may be harmful (e.g. renal insufficiency, elderly patients) DULCOLAX should be discontinued and only be restarted under medical supervision.

Patients may experience haematochezia (blood in stool) that is generally mild and self-limiting.

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 related to the constipation and not necessarily to the administration of DULCOLAX itself.

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

Children should not take DULCOLAX without medical advice.

One coated tablet contains 33.2 mg lactose, resulting in 66.4 mg lactose per maximum recommended daily dose for treatment of constipation in adults and children over 10 years of age. For radiographic examination this will result in 132.8 mg per maximum recommended daily dose in adults. Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, should not take this medicine.

One coated tablet contains 23.4 mg sucrose (saccharose), resulting in 46.8 mg sucrose (saccharose) per maximum recommended daily dose for treatment of constipation in adults and children over 10 years of age. For radiographic examination this will result in 93.6 mg per maximum recommended daily dose in adults. Patients with the rare hereditary condition of fructose intolerance should not take this medicine.

### **Fertility Pregnancy and Lactation**

There are no adequate and well-controlled studies in pregnant women. Long experience has shown no evidence of undesirable or damaging effects during pregnancy.

Nevertheless, as with all drugs, DULCOLAX should be taken during pregnancy only on medical advice.

Clinical data show that neither the active moiety of bisacodyl BHPM (bis-(p-hydroxyphenyl)-pyridyl-2-methane) nor its glucuronides are excreted into the milk of healthy lactating human females.

Thus, DULCOLAX can be used during breast-feeding.

No studies on the effect on human fertility have been conducted.

### **Effects on Ability to Drive and Use Machines**

No studies on the effects of DULCOLAX on the ability to drive and use machines have been performed.

However, patients should be advised that due to a vasovagal response (e.g., to abdominal spasm) they may experience dizziness and/or syncope. If patients experience abdominal spasm they should avoid potentially hazardous tasks such as driving or operating machinery.

### **Adverse Events**

The most commonly reported adverse reactions during treatment are abdominal pain and diarrhoea.

#### Immune system disorders

Anaphylactic reactions, angioedema, hypersensitivity.

#### Metabolism and nutrition disorders

Dehydration

#### Nervous system disorders

Dizziness, syncope.

Dizziness and syncope occurring after taking bisacodyl appear to be consistent with a vasovagal response (e.g., to abdominal spasm, defecation).

#### Gastrointestinal disorders

Colitis, abdominal cramps, abdominal pain, diarrhoea, vomiting, nausea, haematochezia (blood in stool), abdominal discomfort, anorectal discomfort.

## Interactions

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of DULCOLAX are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

## Overdosage

### Symptoms

If high doses are taken watery stools (diarrhoea), abdominal cramps and a clinically significant loss of fluid, potassium and other electrolytes can occur.

DULCOLAX, as with other laxatives, when taken in chronic overdose 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.

### Treatment

Within a short time after ingestion of oral forms of DULCOLAX, absorption can be minimized or prevented by 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.

## Medicine Classification

Pharmacy-only Medicine.

## Pharmaceutical Precautions

Store in a safe place out of reach of children.

Store below 30° C

## Package Quantities

*Suppository:* 5mg, 6s;  
10mg, 6s, 50s.

*Tablets:* 5mg, 30s, 100s.

## Further Information

Dulcolax® is a registered trademark

## Excipients

Coated tablets: Lactose monohydrate, maize starch dried, glycerol, magnesium stearate, sucrose, talc, acacia, titanium dioxide, methacrylic acid-methyl methacrylate copolymer (1:1) and methacrylic acid-methyl methacrylate copolymer (1:2), Castor oil, macrogol 6000, iron oxide yellow (E172), beeswax white, carnauba wax, shellac, maize starch (soluble)

Suppositories: Hard fat (Witepsol W45)

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