PRESCRIBING INFORMATION

DULCOLAX®

Bisacodyl

Tablets 5 mg
Suppositories 5 mg (children) and 10 mg (adult)

Boehringer Ingelheim Std.

Stimulant Laxative

Boehringer Ingelheim Canada Ltd.
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Bisacodyl

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Oral	tablet 5 mg	lactose, sucrose, and tartrazine (yellow). Please refer to the complete listing of ingredients in the Dosage Forms, Composition and Packaging section.
Rectal	suppositories 5 mg, 10 mg	hard fat

INDICATIONS AND CLINICAL USE

DULCOLAX is indicated for:

- Relief of occasional constipation
- Under medical supervision, for the preparation of diagnostic procedures, in pre- and postoperative treatment, and in conditions which require defecation to be facilitated.

CONTRAINDICATIONS

DULCOLAX is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the product monograph.
- Patients with ileus, intestinal obstruction, acute abdominal conditions like acute appendicitis, acute inflammatory bowel diseases, severe abdominal pain associated with nausea and vomiting which may be indicative of more severe conditions.
- Severe dehydration.
- In case of rare hereditary conditions that may be incompatible with an excipient of the product (lactose or sucrose). See WARNINGS AND PRECAUTIONS.

WARNINGS AND PRECAUTIONS

General

As with all laxatives, DULCOLAX should not be taken on a continuous daily basis or for extended periods without investigating the cause of constipation. Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

Do not use DULCOLAX in the presence of abdominal pain, nausea, fever or vomiting, or within two hours of another medicine since the desired effect of the other medicine may be reduced.

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 and should be used in these conditions under medical advice or as directed by a physician.

DULCOLAX coated tablets contain lactose and sucrose. One coated tablet contains 33.2 mg lactose and 23.4 mg sucrose (saccharose), resulting in 66.4 mg lactose and 46.8 mg sucrose per maximum recommended daily dose for treatment of constipation. For preparation of diagnostic procedure this will result in 132.8 mg of lactose and 93.6 mg sucrose per maximum recommended daily dose in adults. Patients with the rare hereditary conditions of galactose intolerance, e.g. galactosaemia, or fructose intolerance should not take DULCOLAX tablets.

The tablet formulation contains tartrazine as a colouring agent; this agent may cause allergic reactions. Patients with tartrazine allergy should not take Dulcolax tablets.

Dependence/Tolerance

Since extended use of any laxative can cause dependence for bowel function, do not take for more than one week unless directed by a health professional. If the use of DULCOLAX every day for a week does not result in a bowel movement, a doctor should be consulted immediately.

Special Populations

Pregnant Women: There are no adequate and well-controlled studies in pregnant women. For use during pregnancy, it is recommended that medical advice from a physician first be obtained. As with all medications, DULCOLAX should only be taken during pregnancy on medical advice.

Nursing Women: 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.

Fertility: No studies on the effect of 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.

Pediatrics: Children should not be given DULCOLAX without medical advice.

ADVERSE REACTIONS

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

Immune system disorders
Hypersensitivity, anaphylactic reactions, angioedema.

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

DRUG 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.

DULCOLAX tablets have an enteric coating and should not be taken together with products

reducing the acidity of the upper gastrointestinal tract, such as milk, antacids or proton pump inhibitors, in order not to prematurely dissolve the enteric coating.

DOSAGE AND ADMINISTRATION

Dosing Considerations

DULCOLAX should be used under medical supervision for the preparation of diagnostic procedures, in pre- and postoperative treatment and in medical conditions which require defecation to be facilitated.

Recommended Dose and Dosage Adjustment

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

- **For constipation**

Adults and children over 12 years: Take one to two coated tablets (5 -10 mg) orally or one adult suppository (10 mg) rectally.
Children 6-12 years: Give one coated tablet (5 mg) orally or one paediatric suppository (5 mg) rectally.
Children under 6 years: Use only as directed by your doctor.

- **For diagnostic procedures or pre-operatively to achieve complete evacuation of the intestine:**

Adults: Two to four coated tablets (10 - 20 mg) orally the night before the procedure, followed by one suppository (10 mg) in the morning of the procedure.
Children 6 years and over: One coated tablet (5 mg) orally at bedtime, and one paediatric suppository (5 mg) inserted rectally the following morning.

Administration

It is recommended to take DULCOLAX coated tablet(s) at night to have a bowel movement the following morning.

Tablets have a special coating and therefore 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.

Tablets should be swallowed whole with an adequate amount of fluid.

Suppositories should take from about 15 minutes to 1 hour to stimulate a bowel movement. They should be unwrapped and inserted into the rectum pointed end first.

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.

For management of a suspected overdose, contact your regional Poison Control Centre.

STORAGE AND STABILITY
Store out of the reach of children.
Tablets: Store at room temperature (15 – 30°C).
Suppositories: Store at room temperature (15 – 25°C).

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each enteric coated tablet contains bisacodyl 5 mg.
Non-medicinal ingredients: acacia, beeswax, carnauba wax, corn starch, dibutyl phthalate, eudragit, glycerin, lactose, magnesium stearate, polyethylene glycol, sucrose, talc, tartrazine (yellow) and titanium dioxide.

Each rectal suppository contains bisacodyl 5 mg (pediatric) or 10 mg (adult).
Non-medicinal ingredient: hard fat.

Coated tablets (5 mg): packages of 10, 30, 60, and 100.
Suppositories (10 mg): boxes of 3, 6, and 100.
Pediatric suppositories (5 mg): boxes of 3.