

## PRESCRIBING INFORMATION

**DULCOLAX<sup>®</sup>**

Bisacodyl

Tablets 5 mg

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

Boehringer Ingelheim Std.

Stimulant Laxative

Boehringer Ingelheim Canada Ltd.  
5180 South Service Rd.  
Burlington, ON L7L 5H4

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# DULCOLAX®

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.

**PART III: CONSUMER INFORMATION****Dulcolax<sup>®</sup>  
Bisacodyl Suppositories**

This leaflet is part of the "Prescribing Information" published for DULCOLAX and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DULCOLAX. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

DULCOLAX is used for relief of occasional constipation.

Under medical supervision DULCOLAX is also used to empty the bowels before and after surgery and before examination.

**What it does:**

DULCOLAX belongs to a group of medicines known as stimulant laxatives. DULCOLAX stimulates the bowel muscles while also accumulating water in the intestines. The effect is to soften the stool and to make it pass through more quickly.

**When it should not be used:**

- If you have severe abdominal pain associated with nausea and vomiting.
- If you have intestinal obstruction (ileus), acute inflammatory bowel disease, or appendicitis.
- If you are suffering from severe dehydration.
- If you are allergic to the drug or any component of it (see non-medicinal ingredients)

**What the medicinal ingredient is:**

Bisacodyl

**What the important non-medicinal ingredients are:**

Suppositories contain: hard fat.

**What dosage forms it comes in:**

Tablets 5 mg

Suppositories 5 mg (children) and 10 mg (adults).

**WARNINGS AND PRECAUTIONS****BEFORE you use DULCOLAX talk to your doctor or pharmacist:**

- If you have ever had an allergic reaction to this or any other medicines.
- If you have any pain in the lower abdomen or if you have stomach cramps, fever, nausea or vomiting.
- If you are pregnant.
- If you have taken DULCOLAX already for a week without any effect.

- If you are taking any other medications, including those available without a prescription, herbal and complementary medicines.

Do not give DULCOLAX to a child unless the doctor tells you to.

A laxative should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced.

You may experience dizziness and/ or fainting (syncope) caused by a malaise triggered by abdominal spasm. If you experience abdominal spasm, avoid hazardous tasks such as driving or operating machinery.

**INTERACTIONS WITH THIS MEDICATION**

Drugs that may interact with DULCOLAX include: diuretics (eg. hydrochlorothiazide), adreno-corticosteroids (eg. hydrocortisone, prednisone), and cardiac glycosides (eg. digoxin).

This is not an all-inclusive list of examples. Tell your doctor and pharmacist what prescription and nonprescription medications, vitamins and herbals you are taking.

**PROPER USE OF THIS MEDICATION**

**Do not take more than the recommended daily dose. Overuse or extended use of any laxative can cause dependence for bowel function, do not take for more than a week without consulting a physician.**

**Usual dose:**

For relief of constipation:

Adults and children over 12 years: one adult suppository (10 mg)

Children 6-12 years: one children suppository (5 mg).

Children under 6 years: Use only as directed by your doctor.

Suppositories should take from about 15 minutes to 1 hour to stimulate a bowel movement.

One DULCOLAX 5 mg or 10 mg suppository inserted as described below:

**USAGE:** Unwrap the suppository from its foil covering. Dip the tip of the suppository for a few seconds in lukewarm water to soften the exterior. Lie down on your side and raise your opposite knee to your chest. Relax the buttock just before inserting the suppository to ease insertion. Gently insert suppository, lubricated pointed end first, high into rectum so that it will not slip out. Push the flat end of the suppository sideways to make sure that part of it touches the wall of the rectum. Continue to lie down for a few minutes and hold the buttocks together to allow the suppository to dissolve in the rectum. Try to retain the suppository in the rectum as long as possible.



**Overdose:**

If high doses are taken, watery stool (diarrhoea), abdominal cramps, and loss of fluid, potassium and other minerals can occur. DULCOLAX when taken in chronic overdose may cause chronic diarrhoea, abdominal pain, kidney damage, and muscle weakness.

In case of overdose, contact your physician, pharmacist, or your regional Poison Control Centre immediately.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

DULCOLAX may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away: abdominal discomfort (including abdominal cramps, abdominal pain, nausea, vomiting or diarrhoea), dehydration (with symptoms such as dry, sticky mouth, thirst), dizziness, fainting (syncope), swelling of the colon (large bowel), anorectal discomfort (discomfort involving the anus and rectum) and haematochezia (blood in stools).

If you have any of the following symptoms, stop taking DULCOLAX and call your doctor immediately: allergic reactions (including swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing).

*This may not be a complete list of side effects. For any unexpected effects while taking DULCOLAX, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep out of the reach of children. Store in a cool, dry place at room temperature (15 - 25°C).

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345  
By toll-free fax: 866-678-6789  
Online: [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)  
By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:  
Canada Vigilance National Office  
Marketed Health Products Safety and Effectiveness  
Information Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Tunney's Pasture, AL 0701C  
Ottawa ON K1A 0K9

*NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

This document plus the full product monograph (or prescribing information), prepared for health professionals can be found at: <http://www.boehringer-ingelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633 (Medical Information).

Please visit our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

Last revised: August 16, 2013

**PART III: CONSUMER INFORMATION****Dulcolax<sup>®</sup>**  
**Bisacodyl Tablets**

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**What it does:**

DULCOLAX belongs to a group of medicines known as stimulant laxatives. DULCOLAX stimulates the bowel muscles while also accumulating water in the intestines. The effect is to soften the stool and to make it pass through more quickly.

**When it should not be used:**

- If you have severe abdominal pain associated with nausea and vomiting.
- If you have intestinal obstruction (ileus), acute inflammatory bowel disease, or appendicitis.
- If you are suffering from severe dehydration.
- If you are allergic to the drug or any component of it (see non-medicinal ingredients).
- If you have a rare hereditary condition of galactose or fructose intolerance you should not use DULCOLAX tablets.
- If you are allergic to the tartrazine colouring agent, you should not use DULCOLAX tablets.

**What the medicinal ingredient is:**

Bisacodyl

**What the important non-medicinal ingredients are:**

Enteric coated tablets contain: acacia, beeswax, carnauba wax, corn starch, dibutyl phthalate, eudragit, glycerine, lactose, magnesium stearate, polyethylene glycol, sucrose, talc, tartrazine (yellow), and titanium dioxide.

**What dosage forms it comes in:**

Tablets 5 mg

Suppositories 5 mg (children) and 10 mg (adults).

**WARNINGS AND PRECAUTIONS**

**BEFORE you use DULCOLAX talk to your doctor or**

**pharmacist:**

- If you have ever had an allergic reaction to this or any other medicines.
- If you have any pain in the lower abdomen or if you have stomach cramps, fever, nausea or vomiting.
- If you are pregnant.
- If you have taken DULCOLAX already for a week without any effect.
- If you are taking any other medications, including those available without a prescription, herbal and complementary medicines.

Do not give DULCOLAX to a child unless the doctor tells you to.

A laxative should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced.

You may experience dizziness and/ or fainting (syncope) caused by a malaise triggered by abdominal spasm. If you experience abdominal spasm, avoid hazardous tasks such as driving or operating machinery.

**INTERACTIONS WITH THIS MEDICATION**

Drugs that may interact with DULCOLAX include: diuretics (eg. hydrochlorothiazide), adreno-corticosteroids (eg. hydrocortisone, prednisone), cardiac glycosides (eg. digoxin), antacids or certain proton pump inhibitors (eg. lansoprazole, omeprazole, pantoprazole).

Do not take indigestion remedies at the same time of day as DULCOLAX tablets. Do not take with milk or antacid.

This is not an all-inclusive list of examples. Tell your doctor and pharmacist what prescription and nonprescription medications, vitamins and herbals you are taking.

**PROPER USE OF THIS MEDICATION**

**Do not take more than the recommended daily dose. Overuse or extended use of any laxative can cause dependence for bowel function, do not take for more than a week without consulting a physician.**

Do not crush or chew tablets; swallow them whole. Do not take with milk or antacid.

**Usual dose:** For relief of constipation:

Adults and children over 12 years: one to two tablets

Children 6-12 years: one tablet

Children under 6 years: Use only as directed by your doctor.

Take DULCOLAX tablets at night to have a bowel movement the next morning.

Tablets should be swallowed whole with an adequate amount of liquid (NOT MILK).

**Overdose:**

If high doses are taken, watery stool (diarrhoea), abdominal cramps, and loss of potassium and other minerals can occur. DULCOLAX when taken in chronic overdose may cause chronic diarrhoea, abdominal pain, kidney damage, and muscle weakness.

In case of overdose, contact your physician, pharmacist, or your regional Poison Control Centre immediately.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

DULCOLAX may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away: abdominal discomfort (including abdominal cramps, abdominal pain, nausea, vomiting or diarrhoea), dehydration (with symptoms such as dry, sticky mouth, thirst), dizziness, fainting (syncope), swelling of the colon (large bowel), anorectal discomfort (discomfort involving the anus and rectum), and haematochezia (blood in stools).

If you have any of the following symptoms, stop taking DULCOLAX and call your doctor immediately: allergic reactions (including swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing).

*This may not be a complete list of side effects. For any unexpected effects while taking DULCOLAX, contact your doctor or pharmacist.*

**HOW TO STORE IT**

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 By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:  
**Canada Vigilance National Office**  
**Marketed Health Products Safety and Effectiveness**  
**Information Bureau**  
**Marketed Health Products Directorate**  
**Health Products and Food Branch**  
**Health Canada**  
**Tunney's Pasture, AL 0701C**  
**Ottawa ON K1A 0K9**

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**MORE INFORMATION**

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