

PRESCRIBING INFORMATION

DULCOLAX[®]

Bisacodyl

Tablets 5 mg
Suppositories 10 mg

Manufacturer's Standard

Stimulant Laxative

sanofi-aventis Canada Inc.
2905 Louis-R.-Renaud Place
Laval, Quebec H7V 0A3

Date of Revision:
November 7, 2017

Submission Control No:210082

CCDS: 0074-07

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DULCOLAX[®]

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Oral	tablet 5 mg	acacia, white wax, carnauba wax, corn starch (dried/soluble), methacrylic acid and ethyl acrylate copolymer dispersion, glycerine, lactose monohydrate, magnesium stearate, polyethylene glycol, sucrose, talc, glyceryl monostearate, triethyl citrate, polysorbate 80, D&C Yellow #10 Aluminum Lake, D&C red no. 30, povidone, sodium benzoate, methylparaben, propylparaben and titanium dioxide.
Rectal	suppository 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 Prescribing Information.
- 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 patients with 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 34.9 mg lactose and 21.4 mg sucrose (saccharose), resulting in 69.8 mg lactose and 42.8 mg sucrose per maximum recommended daily dose for treatment of constipation. For preparation of diagnostic procedure this will result in 139.6 mg of lactose and 85.6 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.

Stimulant laxatives including DULCOLAX do not help with weight loss. ¹

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 (including ischaemic colitis and necrotizing colitis).²

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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.

The concomitant use of other laxatives may enhance the gastrointestinal side effects of DULCOLAX.²

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) daily, orally or one adult suppository (10 mg) daily, rectally.

Children 6-12 years: Give one coated tablet (5 mg) daily, orally.

- **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.

Administration

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

It is recommended to start with the lowest dose (1 tablet). The dose may be adjusted up to a maximum single dose of 2 tablets to produce regular stools. The maximum daily dose should not be exceeded.

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, white wax, carnauba wax, corn starch (dried/soluble), methacrylic acid and ethyl acrylate copolymer dispersion, glycerine, lactose monohydrate, magnesium stearate, polyethylene glycol, sucrose, talc, glyceryl monostearate, triethyl citrate, polysorbate 80, D&C Yellow #10 Aluminum Lake, D&C red no. 30, povidone, sodium benzoate, methylparaben, propylparaben and titanium dioxide.

Each rectal suppository contains bisacodyl 10 mg (adult).

Non-medicinal ingredient: hard fat.

Coated tablets (5 mg):-blister packs of 10, 30, 60, and bottles of 100.

Suppositories (10 mg): blister packs of 3, 6, and 100.

PART III: CONSUMER INFORMATION

Dulcolax[®] **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 10 mg

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.

Do not take DULCOLAX for weight loss.

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) daily.

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

One DULCOLAX 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 and sight of children. Store in a cool, dry place at room temperature (15 - 25°C).

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhpm/mpe/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the DULCOLAX Prescribing Information, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: **1-800-265-7927**.

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

This leaflet was prepared by sanofi-aventis Canada Inc.
Last revised: November 7, 2017

PART III: CONSUMER INFORMATION

Dulcolax[®] 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.

What the medicinal ingredient is:

Bisacodyl

What the important non-medicinal ingredients are:

acacia, white wax, carnauba wax, corn starch (dried/soluble), methacrylic acid and ethyl acrylate copolymer dispersion, glycerine, lactose monohydrate, magnesium stearate, polyethylene glycol, sucrose, talc, glyceryl monostearate, triethyl citrate, polysorbate 80, D&C Yellow #10 Aluminum Lake, D&C red no. 30, povidone, sodium benzoate, methylparaben, propylparaben and titanium dioxide.

What dosage forms it comes in:

Tablets 5 mg
Suppositories 10 mg

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.

Do not take DULCOLAX for weight loss.

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 antacids.

This is not an all-inclusive list of examples. Tell your doctor and pharmacist what prescription and non-prescription 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 antacids.

Usual dose: For relief of constipation

Adults and children over 12 years: One to two tablets daily.
Children 6-12 years: One tablet daily.

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

It is recommended to start with the lowest dose (1 tablet). The dose may be adjusted up to a maximum single dose of 2 tablets to produce regular stools. The maximum daily dose should not be exceeded.

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.

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