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.

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), ano-rectal 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
By email: 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 DULCOLAX 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: January 13, 2014
**PART III: CONSUMER INFORMATION**

**Dulcolax®**

**Bisacodyl Tablets**

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).
- 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 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.

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 nonprescription medications, vitamins and herbs 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.

**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
- **By email:** 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 DULCOLAX 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: January 13, 2014