

### 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 used in preparation for diagnostic procedures, before and after surgery and in conditions which require defecation to be facilitated.

##### 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 or breast-feeding.
- If you are planning to give DULCOLAX to a child.
- 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.
- A laxative should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced.

#### INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with DULCOLAX include: diuretics, adreno-corticosteroids, cardiac glycosides, antacids or certain proton pump inhibitors.

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

#### PROPER USE OF THIS MEDICATION

**Do not take more than the recommended daily dose. 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 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**

While using DULCOLAX some patients have experienced abdominal discomfort (including abdominal cramps, abdominal pain, nausea or diarrhoea).  
Allergic reactions have been reported.

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

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: December 18, 2008

**HOW TO STORE IT**

Keep out of the reach of children. Store in a cool, dry place at room temperature (15 – 30°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. 4633 (Medical Information)