PRESCRIBING INFORMATION

# DULCOLAX FOR WOMEN®

Bisacodyl Tablets USP 5mg

Stimulant Laxative

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**DULCOLAX®**
**FOR WOMEN**
Bisacodyl

## PART I: HEALTH PROFESSIONAL INFORMATION

### SUMMARY PRODUCT INFORMATION

| Route of Administration | Dosage Form / Strength | Clinically Relevant Nonmedicinal Ingredients |
|---|---|---|
| Oral | tablet 5 mg | acacia, ammonium hydroxide, carnauba wax, corn starch, D&C Red #27 aluminum lake, FD&C Blue #2 aluminum lake, FD&C Yellow #6 aluminum lake, iron oxide black, glycerin, glyceryl monostearate, lactose monohydrate, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, methylparaben, modified starch, polyethylene glycol, polysorbate 80, povidone, propylene glycol, propylparaben, shellac, sodium benzoate, sucrose, talc, titanium dioxide, triethyl citrate, white wax |

### INDICATIONS AND CLINICAL USE

DULCOLAX FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN. 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 FOR WOMEN itself.

DULCOLAX FOR WOMEN 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 FOR WOMEN tablets.

Stimulant laxatives including DULCOLAX FOR WOMEN do not help with weight loss.

### 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 FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN without medical advice.

## ADVERSE REACTIONS

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

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, diarrhea, nausea, haematochezia (blood in stool), vomiting, abdominal discomfort, anorectal discomfort, colitis (including ischaemic colitis and necrotizing colitis).

The concomitant use of diuretics or adreno-corticosteroids may increase the risk of electrolyte imbalance if excessive doses of DULCOLAX FOR WOMEN are taken.

Electrolyte imbalance may lead to increased sensitivity to cardiac glycosides.

DULCOLAX FOR WOMEN 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 FOR WOMEN.

## DOSAGE AND ADMINISTRATION

### Dosing Considerations

DULCOLAX FOR WOMEN 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

*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.

### Administration

It is recommended to take DULCOLAX FOR WOMEN 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.

## OVERDOSAGE

**Symptoms**
If high doses are taken, watery stools (diarrhea), abdominal cramps, and a clinically significant loss of fluid, potassium and other electrolytes can occur.

DULCOLAX FOR WOMEN, as with other laxatives, when taken in chronic overdose may cause chronic diarrhea, abdominal pain, hypokalemia, secondary hyperaldosteronism and renal calculi. Renal tubular damage, metabolic alkalosis and muscle weakness secondary to hypokalemia have also been described in association with chronic laxative abuse.

**Treatment**
Within a short time after ingestion of oral forms of DULCOLAX FOR WOMEN, 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).

## DOSAGE FORMS, COMPOSITION AND PACKAGING

Each enteric coated tablet contains bisacodyl 5 mg.
Non-medicinal ingredients: acacia, ammonium hydroxide, carnauba wax, corn starch, D&C Red #27 aluminum lake, FD&C Blue #2 aluminum lake, FD&C Yellow #6 aluminum lake, iron oxide black, glycerin, glyceryl monostearate, lactose monohydrate, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, methylparaben, modified starch, polyethylene glycol, polysorbate 80, povidone, propylene glycol, propylparaben, shellac, sodium benzoate, sucrose, talc, titanium dioxide, triethyl citrate, white wax

Coated tablets (5 mg): blister packs of 25 and 50.

**PART III: CONSUMER INFORMATION**

**Dulcolax®**
**FOR WOMEN**
Bisacodyl Tablets USP 5mg

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

## ABOUT THIS MEDICATION

**What the medication is used for:**
DULCOLAX FOR WOMEN is used for relief of occasional constipation.

**What it does:**
DULCOLAX FOR WOMEN belongs to a group of medicines known as stimulant laxatives. DULCOLAX FOR WOMEN 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 bisacodyl or any other ingredients in this product.
- If you have a rare hereditary condition of galactose or fructose intolerance you should not use DULCOLAX FOR WOMEN tablets.

**What the medicinal ingredient is:** Bisacodyl

**What the important non-medicinal ingredients are:**
acacia, ammonium hydroxide, carnauba wax, corn starch, D&C Red #27 aluminum lake, FD&C Blue #2 aluminum lake, FD&C Yellow #6 aluminum lake, iron oxide black, glycerin, glyceryl monostearate, lactose monohydrate, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, methylparaben, modified starch, polyethylene glycol, polysorbate 80, povidone, propylene glycol, propylparaben, shellac, sodium benzoate, sucrose, talc, titanium dioxide, triethyl citrate, white wax

**What dosage forms it comes in:**
Tablets 5 mg

## WARNINGS AND PRECAUTIONS

**BEFORE you use DULCOLAX FOR WOMEN 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 FOR WOMEN 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 FOR WOMEN to a child less than 6 years of age 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 WOMEN 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 FOR WOMEN include: diuretics (eg. hydrochlorothiazide), adrenocorticosteroids (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 FOR WOMEN 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 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 (12 years and older): one to two tablets daily.

Take DULCOLAX FOR WOMEN 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 the maximum recommended single dose of 2 tablets to produce regular stools.

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

**Overdose:**
If high doses are taken, watery stool (diarrhea), abdominal cramps, and loss of potassium and other minerals can occur.
DULCOLAX FOR WOMEN when taken in chronic overdose may cause chronic diarrhea, 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 FOR WOMEN 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 diarrhea), 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 FOR WOMEN 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 FOR WOMEN, 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 – 30°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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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 DULCOAX FOR WOMEN 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.

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