

## New Zealand Consumer Medicine Information

### **DULCOLAX®**

#### **Tablets and Suppositories**

#### ***Bisacodyl***

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### **What is in this leaflet**

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This leaflet answers some common questions about DULCOLAX. It does not contain all available information, nor does it take the place of talking to your doctor or pharmacist. Keep this information with your DULCOLAX. You may need to read it again.

#### ***To find out more about DULCOLAX***

You should ask your doctor or pharmacist if you have any questions about DULCOLAX or if you have any trouble before, during or after using DULCOLAX.

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### **What DULCOLAX is used for**

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DULCOLAX is mainly used for the treatment of constipation.

Under medical supervision, DULCOLAX can be used for the evacuation of the bowel before a radiological examination or as an enema alternative.

DULCOLAX works by acting on the lining of the lower bowel to stimulate movement and promotes accumulation of water into the bowel to produce soft formed stools.

Dulcolax is ineffective in altering the digestion or absorption of calories or essential nutrients in the small intestine.

Stimulant laxatives including DULCOLAX do not help with weight loss.

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### **Before you use DULCOLAX**

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#### ***When you must not use DULCOLAX***

Do not use DULCOLAX if you are allergic to bisacodyl or any of the other ingredients in DULCOLAX. All the ingredients in DULCOLAX tablets and DULCOLAX suppositories are listed under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use DULCOLAX if you have, or have had, any of the following conditions:

- an acute abdominal condition including appendicitis
- acute inflammatory bowel disease
- severe abdominal pain associated with nausea and vomiting
- blockage of the bowel (ileus)
- a blockage of the intestine
- severe dehydration

If you are uncertain as to whether you have, or have had, any of these conditions, you should raise any concerns with your doctor or pharmacist.

Do not use DULCOLAX after the expiry date (EXP) on the foil, blister pack or carton. If you use it after the expiry date has passed, it may not work as well.

Do not use DULCOLAX if the packaging is torn or shows signs of tampering.

### ***Before you start to use DULCOLAX***

Before using DULCOLAX suppositories, you must tell your doctor or pharmacist if you have, or have had any medical conditions including:

- an anal fissure (painful tear in the lining of the anus)
- ulcerative proctitis (inflammation of the rectum [back passage]).

Suppositories may cause pain and local irritation, especially if you have an anal fissure (painful tear in the lining of the anus) or ulcerative proctitis (inflammation of the rectum).

If you are uncertain as to whether you have, or have had any of these conditions, you should raise any concerns with your doctor or pharmacist.

Before using DULCOLAX, you must tell your doctor or pharmacist if you are taking any other medicines obtained with or without a doctor's prescription.

In particular, you should tell your doctor or pharmacist if you are taking:

- diuretics (medicines that increase urine volume)
- corticosteroids
- medicines which stimulate the heart e.g. digoxin.

It is important to discuss this with your doctor or pharmacist because DULCOLAX may not work as well in the presence of some other medicines or side effects may be increased.

Use of Dulcolax with other laxatives may enhance gastrointestinal side effects.

After taking DULCOLAX, avoid straining while passing a bowel motion.

Dizziness and fainting while straining have been reported in patients who have taken DULCOLAX. It is not known if DULCOLAX can cause dizziness or fainting.

You may experience blood in the stool while using DULCOLAX. This is generally mild and self-limiting. Tell your doctor if you notice this and it worries you.

DULCOLAX is recommended for short-term use only. If symptoms persist, seek medical advice.

Long-term use of DULCOLAX is not recommended. If you use DULCOLAX every day, you should consult with your doctor to find out the cause of your constipation.

Long-term and excessive use of DULCOLAX may cause an imbalance of salts in the body (including low potassium), muscle weakness and kidney problems. Loss of fluids from the body can cause dehydration. Symptoms of dehydration include thirst and passing less urine than normal. In patients experiencing fluid loss where

dehydration may be harmful (for example, kidney problems, elderly patients) DULCOLAX should be stopped and only restarted under medical supervision.

Long-term and excessive use may also cause the bowel to become dependent on DULCOLAX for it to produce a bowel motion.

### ***Pregnancy***

As for other medicines, ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of DULCOLAX.

Special care is recommended during pregnancy. The benefits of DULCOLAX must be assessed against any risks. Your doctor will discuss the risks and benefits of using DULCOLAX while you are pregnant.

### ***Breastfeeding***

As for other medicines, ask for your doctor's advice if you are breastfeeding or likely to breastfeed during your course of DULCOLAX. DULCOLAX does not pass into breast milk. Therefore DULCOLAX can be used during breastfeeding.

### ***Children***

DULCOLAX should be used in children aged 10 years or younger only on medical advice.

DULCOLAX tablets may be used in children 4 years of age and over and are not recommended for use in children under 4 years of age.

DULCOLAX suppositories may be used in children 10 years of age and under.

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## **Using DULCOLAX tablets and suppositories**

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### ***How to take DULCOLAX tablets***

Swallow DULCOLAX tablets whole with a glass of water. Do not crush or chew DULCOLAX tablets.

Do not take DULCOLAX tablets together with medicines that lower acidity of the upper gastrointestinal tract (stomach). These medicines include antacids, and a group of medicines called proton pump inhibitors. If you think you may be taking any of these medicines, please speak with your doctor or pharmacist.

Do not take milk or antacids within 1 hour of taking DULCOLAX tablets. These may affect how well DULCOLAX tablets work.

DULCOLAX tablets generally work in 6-12 hours.

### ***How to use DULCOLAX suppositories***

Do not coat the suppository in any lubricant such as paraffin oil or paraffin jelly. By warming the suppository in the hand before it is removed from the foil wrapper, sufficient lubrication will be produced.

Follow the directions below to use DULCOLAX suppositories:

1. Wash your hands thoroughly with soap and water.

2. Remove all of the foil wrapper from the suppository.
3. Lie on your side and raise your knee to your chest.
4. Push the suppository gently and slowly, pointed end first, into the rectum (back passage).
5. Throw away used materials and wash your hands thoroughly.

DULCOLAX suppositories generally work in about 20 minutes, but may take up to 45 minutes.

If you are not sure how to use a suppository, ask your doctor or pharmacist for advice.

### ***Recommended dose of DULCOLAX***

DULCOLAX should be taken as needed to relieve constipation. It is recommended to start with the lowest dose. The dose may be adjusted up to the maximum recommended dose to produce regular stools. The maximum daily dose should not be exceeded.

#### DULCOLAX Tablets

Adults and children over 10 years:

one or two DULCOLAX tablets at night

Children 4 to 10 years:

one DULCOLAX tablet at night

DULCOLAX tablets are not recommended in children under 4 years of age.

#### DULCOLAX Suppositories

Adults and children over 10 years:

one DULCOLAX suppository (10 mg)

Children under 10 years of age:

Use only on medical advice.

If your doctor or pharmacist has changed the recommended dose, you should ask for further information from your doctor or pharmacist.

### ***Overdose***

Seek medical advice if you have used more than the recommended or prescribed dose of DULCOLAX.

Advice can be provided by a doctor, pharmacist or Poisons Information Centre (telephone 0800 764766).

If you have taken too much DULCOLAX, you may have diarrhoea, abdominal cramps, fluid loss, and an imbalance of salts in the body (including low potassium).

As with other laxatives, persistent overdose may cause diarrhoea, abdominal pain, imbalance of salts in the body (including low potassium), secondary hyperaldosteronism and kidney stones. If an imbalance of salts (low potassium) occurs, then kidney disease, metabolic alkalosis and muscle weakness may be experienced.

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## **While you are using DULCOLAX**

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### ***Things to consider:***

Tell your doctor or pharmacist if you begin taking any other medicine while you are using DULCOLAX. This applies to all medicines obtained with or without a doctor's prescription.

Tell all doctors and pharmacists who are treating you that you are using DULCOLAX.

Drink plenty of water while taking laxatives.

An increase in fibre in your diet is recommended, except in cases of medication-induced constipation.

You should discuss with your doctor or pharmacist if you need to increase the fibre in your diet when using DULCOLAX to assist in the treatment of constipation.

### ***Effects on Ability to Drive or Operate Machinery***

Be careful driving or operating machinery until you know how DULCOLAX affects you. Do not drive or operate machinery if you experience dizziness or fainting.

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## **Side effects**

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All medicines carry some risks and all possible risks may not be known at this stage despite thorough testing. Your doctor or pharmacist has weighed the risks of using DULCOLAX against the benefits they expect it will have for you.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of using this medicine.

The following side effects of DULCOLAX may occur:

- colitis including ischaemic colitis
- abdominal discomfort
- abdominal cramps
- abdominal pain
- nausea
- vomiting
- diarrhoea
- anorectal discomfort
- blood in the stools
- dehydration
- dizziness
- fainting

Abdominal pain and diarrhoea are the most commonly reported side effects. These side effects are usually mild and short lived. Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- rash, itching or hives on the skin,
- swelling of the face, lips, tongue or other parts of the body,
- shortness of breath, wheezing or trouble breathing.

These are the symptoms of life-threatening allergic (anaphylactic) reactions. These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## **After using DULCOLAX**

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### ***Storage***

DULCOLAX tablets and DULCOLAX suppositories should be kept in a cool dry place where the temperature stays below 30°C.

Do not store in direct sunlight or heat. Store DULCOLAX in a safe place where children cannot reach it.

### ***Disposal***

Unused DULCOLAX tablets and DULCOLAX suppositories should be returned to your pharmacist so they can be disposed of safely.

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## **Product Description**

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### ***What is DULCOLAX***

DULCOLAX is the brand name of your medicine.

DULCOLAX is available as sugar-enteric coated tablets. These tablets are smooth, round, shiny and brownish-yellow in colour.

Each tablet contains 5 mg of bisacodyl and is available in blister packs of, 30, 100 and 200 tablets.

DULCOLAX is also available as suppositories containing 10 mg of bisacodyl.

Foil-wrapped DULCOLAX suppositories, each containing 10 mg of bisacodyl, are available in packs of 6, 10 and 50 suppositories. Standard DULCOLAX suppositories are torpedo-shaped, smooth and white or slightly yellowish in colour.

All foil wrapping of DULCOLAX suppositories carries the name DULCOLAX.

Both DULCOLAX tablets and DULCOLAX suppositories are available from your local pharmacy without prescriptions.

### ***Ingredients***

Each DULCOLAX tablet contains 5 mg of bisacodyl and the following ingredients: lactose, maize starch, glycerol, magnesium stearate, sucrose, purified talc, acacia, titanium dioxide, methacrylic acid copolymer, castor oil, macrogol 6000, iron oxide yellow CI77492, white beeswax, carnauba wax, shellac, and maize starch (soluble).

Each DULCOLAX suppository contains 10 mg of bisacodyl with hard fat as the suppository base.

### ***Supplier***

DULCOLAX tablets are supplied in New Zealand by:

sanofi-aventis new zealand ltd  
Level 8, James and Wells Tower  
56 Cawley Street  
Ellerslie, Auckland  
New Zealand

Toll-free: 0800 283 684

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