

New Zealand Consumer Medicine Information

Dulcolax[®] **Tablets and Suppositories** ***Bisacodyl***

What is in this leaflet

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.

What DULCOLAX is used for

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. This movement produces soft formed stools.

Before you use DULCOLAX

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.

If you are not sure if you have these allergies, you should raise those concerns with your doctor or pharmacist.

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
- a condition of the intestine called 'ileus'
- an intestinal obstruction
- severe dehydration
- galactose intolerance
- fructose intolerance.

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 of the following conditions:

- 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 [back passage]).

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.

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.

Intestinal loss of fluids can promote dehydration. Symptoms may include thirst and excessive urination. If you suffer 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.

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. It 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.

Using DULCOLAX tablets and suppositories

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

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 60 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.

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. The preferred dosage form for this age group is a suppository.

DULCOLAX Suppositories

Adults and children over 10 years:

one standard DULCOLAX suppository (10 mg)

Children 4 to 10 years:

one DULCOLAX children's suppository (5 mg)

Children under 10 years of age:

Use only on medical advice. The preferred dosage form for this age group is a suppository.

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).

As with other laxatives, signs of overdose may include diarrhoea and abdominal cramps as well as other medical problems caused by a loss of salts and water from your body.

While you are using DULCOLAX

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.

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

When used as recommended, and when there are no side effects, DULCOLAX is not known to have any effect on the ability to drive or operate machinery.

Side effects

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
- abdominal discomfort, including cramps and pain
- nausea
- vomiting
- diarrhoea
- blood in the stools
- dehydration
- anal discomfort

More serious side effects include:

- allergic reactions, such as swelling of the face, lips, mouth, tongue or throat
- difficulty in swallowing or breathing
- skin rashes

If these occur, seek medical attention immediately.

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after using DULCOLAX so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after using DULCOLAX.

After using DULCOLAX

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.

Product Description

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 in two strengths - 5 mg and 10 mg.

Foil-wrapped DULCOLAX children's suppositories, each containing 5 mg of bisacodyl, are available in packs of 6 suppositories. DULCOLAX children's suppositories are torpedo-shaped, smooth and white or slightly yellowish in colour.

Foil-wrapped standard DULCOLAX suppositories, each containing 10 mg of bisacodyl, are available in packs of 6 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 children's suppository contains 5 mg of bisacodyl with hard fat as the suppository base.

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

Manufacturer

DULCOLAX tablets are made in France and DULCOLAX suppositories are made in Italy. They are supplied in New Zealand by:

Boehringer Ingelheim NZ Limited
PO Box 76-216
Manukau City
Auckland
Ph 0800 802461

This leaflet was prepared on 12 March 2010.

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