

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. DULCOLAX contains bisacodyl. It belongs to a group of medicines called stimulant laxatives.

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 used for constipation, for conditions that require easier bowel emptying, as well as for bowel emptying during treatment measures and measures to detect diseases (therapeutic and diagnostic interventions) on the intestine.

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.

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.

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) or loss of movement in bowel muscles
- a blockage of the intestine
- severe dehydration

(The contraindication below is only for coated tablets)

- intolerance to or cannot digest some sugars (as the tablet contains small amount of lactose and sucrose)

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 that treat inflammation)
- medicines used to treat heart disease e.g. cardiac glycosides such as digoxin.
- other laxative medicines

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/or fainting have been reported in patients who have taken DULCOLAX. These symptoms can occur as a result of straining during defecation or as a response to abdominal pain and not necessarily due to the use of this medicine.

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. Laxatives should not be taken for an extended period without medical advice. 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 discontinued and should only be reinstated under medical supervision, due to the increased risk of dehydration.

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

Applicable for suppository form:

Using suppositories like DULCOLAX can sometimes be uncomfortable and irritate the area, especially if you have cracking of the skin around your back passage (anal fissures) or if you have inflammation or ulcers around your back passage (ulcerative proctitis).

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.

There is limited data from the use of DULCOLAX in pregnant women. Although there haven't been any signs of harmful effects on pregnancy, use DULCOLAX only, if necessary, under the supervision of your doctor, after the doctor has assessed the expected benefit for her in relation to the possible risk for the fetus. 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 nor its metabolites are passed into breast milk. Therefore, DULCOLAX can be used during breastfeeding. However, use the medicine only, if necessary, under the supervision of your doctor, after your doctor has assessed the expected benefit for you in relation to possible risk to the infant.

Fertility

No studies on the effect on human fertility have been conducted.

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 over.

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

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 (10 to 30 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. DUCOLAX should not be taken continuously, daily or over an extended period without medical advice.

DULCOLAX Tablets

Adults and children 10 years of age and older:

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 tablets are coated. It is recommended to take the coated tablets at night to have a bowel movement the following morning.

DULCOLAX Suppositories

Adults and children 10 years of age and older:

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,

vomiting, mucous, loss of fluid, imbalance of salts in the body (including low potassium and other electrolytes), secondary hyperaldosteronism and kidney stones. If an imbalance of salts (low potassium) occurs, then kidney disease, metabolic alkalosis and muscle weakness may be experienced.

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.

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. 9k

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. If this happens to you, wait until these feeling go away before driving or using machines.

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 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.

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 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:
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks

Auckland
New Zealand
Phone: (09) 918 5100

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