

Package leaflet: Information for the user

Dulcolax enteric-coated tablets 5 mgg, enteric-coated tablets
bisacodyl

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Contact your doctor or pharmacist. If your complaint does not improve after 14 days, or if it even worsens, contact your doctor.

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1. What is Dulcolax and what is it used for?

Dulcolax is a laxative used for difficult bowel movements, also known as constipation. The active ingredient in Dulcolax stimulates the intestinal mucosa. This will accelerate bowel movements, pushing the contents of the intestines forward. Dulcolax enteric-coated tablets provide a soft stool 6 to 12 hours after intake.

For prolonged or recurrent constipation, you can use Dulcolax for several days. Dulcolax is also used in preparation for examinations of your medical condition (e.g., X-rays), before and after surgeries, and in cases where facilitation of bowel movements is needed.

Each enteric-coated tablet has a protective layer that is resistant to stomach acid. As a result, the tablet only disintegrates in the large intestine and starts working there.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You suffer from:

- an intestinal obstruction
- a blockage in the gastrointestinal tract
- an acute appendicitis
- acute inflammations of the intestines
- severe abdominal pain accompanied by nausea and vomiting, which may indicate serious conditions
- severe dehydration symptoms.

You experience sudden severe abdominal pain shortly before taking the tablet.

When should you be extra careful with this medicine?

Dulcolax should not be used day in and day out or for an extended period. If you use Dulcolax every day, the cause of the constipation should be investigated. In that case, contact your doctor.

Prolonged excessive use can lead to a decreased potassium level in the blood, recognizable in severe form by muscle cramps or muscle weakness and fatigue (hypokalemia). Prolonged excessive use can also cause a disorder of the adrenal cortex (secondary hyperaldosteronism), kidney stones, prolonged diarrhea, abdominal pain, and kidney damage.

Fluid loss through the intestines can promote dehydration. Symptoms may include thirst and urinating less or less frequently. If fluid loss could be harmful to you due to reduced kidney function or because you are an older patient, stop using Dulcolax. You may only resume using Dulcolax under medical supervision.

Bloody stools may occur. This is usually harmless and resolves on its own.

Dizziness and fainting may occur, usually in connection with bowel movements or with abdominal pain due to constipation (obstipation).

Use Dulcolax with caution if you are at risk of inflammation of the large intestine, or if you are using other laxatives or polyethylene glycol at the same time. If you suddenly experience abdominal pain, bleeding from the anus, or other symptoms of inflammation of the large intestine due to a problem in blood supply, contact your doctor immediately.

Consult your doctor first before administering Dulcolax to children.

Contact your doctor or pharmacist before using this medicine.

Are you using any other medicines?

Are you using any other medicines besides Dulcolax, or have you done so recently, or is there a possibility that you will use other medicines in the near future? If so, inform your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

You must not use Dulcolax simultaneously with diuretics or adrenal cortex hormones (corticosteroids). When too much Dulcolax is taken, simultaneous use with diuretics or adrenal cortex hormones (corticosteroids) can cause a disturbance in the body's fluid balance.

Disturbance of the body's fluid balance can lead to increased sensitivity to certain heart medicines (cardiac glycosides).

Inform your doctor or pharmacist if you are using other laxatives.

What should you pay attention to with food and drink?

The tablets have a special coating. Simultaneous intake of products that lower the acidity of the upper part of the gastrointestinal tract, such as milk, antacids, or proton pump inhibitors

(medicines used for stomach complaints – such as heartburn – and gastrointestinal ulcers) should be avoided.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

So far, there are no indications of unwanted or harmful effects when using Dulcolax during pregnancy. It is recommended to use Dulcolax during pregnancy only after consulting your doctor. The active substance in Dulcolax does not pass into breast milk. Dulcolax can therefore be safely used during breastfeeding.

Driving and using machines

Dizziness and fainting may occur, usually in connection with bowel movements or with abdominal pain due to constipation. If you experience this, be cautious when participating in traffic or operating machines. It is not known whether Dulcolax, when used as recommended, affects your ability to drive or operate machinery.

Dulcolax tablets contain, among other things, lactose and sucrose (saccharose)

If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

3. How do you use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Constipation

Like other bowel-stimulating agents, Dulcolax should not be used for more than three consecutive days.

It is recommended to start with the lowest dose. The dose can be adjusted to the maximum recommended dose to achieve regular bowel movements. The indicated dosage should not be exceeded.

The recommended dosage is:

Adults: 1 - 2 tablets (5 - 10 mg) per day.

Use in children

Children over 10 years: 1 - 2 tablets (5 - 10 mg) per day.

Children from 2 - 10 years: 1 tablet (5 mg) per day

Dulcolax tablets should not be used by children under 2 years.

Preparation for examinations of your medical condition

The use of Dulcolax as preparation for examinations of your medical condition (e.g. X-rays) should only take place under medical supervision.

Method of use

You can take Dulcolax tablets with a glass of water, tea, or fruit juice. Do not chew. Do not use Dulcolax simultaneously with products that lower the acidity of the upper gastrointestinal tract such as milk, antacids, or proton pump inhibitors (medications used for stomach complaints – such as heartburn – and gastrointestinal ulcers).

You can take the tablet(s) once a day, preferably in the evening. When you take Dulcolax at bedtime, it provides soft stools after about 10 hours without disturbing your sleep. You do not need to strain.

Dulcolax is also available as a suppository (with 10 mg bisacodyl). Dulcolax suppositories work within 10 to 30 minutes after insertion.

Have you taken too much of this medicine?

When high doses of Dulcolax tablets are taken, diarrhea, abdominal cramps, and disturbance of fluid balance may occur.

If you have taken too many Dulcolax tablets, contact your doctor or pharmacist immediately.

Did you forget to take this medicine?

You can take the missed Dulcolax tablet(s). Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

When you stop taking Dulcolax, the constipation may return. Other effects are unlikely.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects can be serious. These side effects are rare (occur in less than 1 in 1,000 users). If you experience any of the following side effects, contact your doctor immediately or go to the emergency department of a nearby hospital:

- sudden fluid accumulation in the skin and mucous membranes (e.g., throat or tongue), difficulty breathing and/or itching and skin rash, often as an allergic reaction (angioneurotic edema)
- severe allergic reaction to certain substances, with a strong drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, reduced consciousness occurring as a result of a sudden strong vasodilation (anaphylactic reaction)
- hypersensitivity reaction
- inflammation of the colon (colitis).

Other side effects

Common side effects (occur in less than 1 in 10 users) may include:

- abdominal cramps
- abdominal pain
- nausea

- diarrhea.

Sometimes occurring side effects (occur in less than 1 in 100 users) may include:

- dizziness*
- burning sensation in the stomach
- bloody stools
- vomiting
- complaints of the anus or rectum.

Rarely occurring side effects (occur in less than 1 in 1000 users) may include:

- Dehydration
- fainting*.

* Dizziness and fainting may occur, usually in connection with bowel movements or with abdominal pain due to constipation (obstipation).

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl.

By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Store below 25°C. Store in the original packaging.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is bisacodyl. Each tablet contains 5 mg of bisacodyl.
- The other substances in this medicine are lactose, dried maize starch, soluble starch, glycerol, magnesium stearate, sucrose (saccharose), talc, acacia, titanium dioxide (E171), methacrylic acid-methyl methacrylate copolymer (1:1) and methacrylic acid-methyl methacrylate copolymer (1:2), castor oil, macrogol 6000, yellow iron oxide (E172), shellac (E904), white beeswax (E901), carnauba wax (E903).

What does Dulcolax look like and what is in a package?

Dulcolax tablets are small, round tablets covered with a yellow, smooth coating. Dulcolax is available in boxes of 10, 30, 60, or 200 tablets in blister packs. Not all mentioned pack sizes are marketed.

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This leaflet was last approved in June 2025.

General information

Constipation occurs when you have difficult, irregular bowel movements. There are several reasons why constipation can occur; for example, due to lack of physical activity, insufficient fiber in the diet, or suppression of the urge. Problems often arise when the daily routine is disrupted, such as during travel and vacations or during busy periods. Illness can also cause constipation. In women, menstruation or pregnancy can be a cause of constipation (obstipation).

You can prevent constipation by eating a lot of fiber-rich products, such as whole grain bread, vegetables, and fruits. These fibers promote bowel function. Drinking plenty of fluids and regular physical activity are also important. If you still suffer from constipation, Dulcolax tablets can help to restart the natural bowel movement process.