

Dulcolax®

sugar-coated tablets

5mg gastro-resistant tablets

For use in adults and children aged 2 years and over

Active substance: bisacodyl

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist have told you.
• Keep this leaflet. You may need to read it again.
• Ask your pharmacist if you need more information or advice.
• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
• You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Dulcolax is and what it is used for
2. What you need to know before you take Dulcolax
3. How to take Dulcolax
4. Possible side effects
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1. WHAT DULCOLAX IS AND WHAT IT IS USED FOR

Dulcolax belongs to a group of medicines called laxatives. Dulcolax is used for relief of constipation, for diseases that call for an easier emptying of the bowel, and for emptying the bowel in preparation for treatments and measures to recognize diseases (therapeutic and diagnostic procedures) of the bowel.

As with other laxatives, Dulcolax should not be taken on a daily basis or for long periods of time without a full diagnostic evaluation of the cause of the constipation.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DULCOLAX

Contraindications:

Do not take Dulcolax

- if you are allergic to the active substance, or any of the other ingredients of this medicine (listed in section 6).
- if you have complaints such as abdominal pain, nausea, vomiting or fever. These may be signs of a serious disease (intestinal stenosis with obstructed intestinal passage, bowel obstruction, an acute abdominal inflammation, acute abdominal pain requiring surgical treatment, such as appendicitis). If you have any such complaints, you should seek medical advice immediately.
- if you have a rare congenital intolerance to lactose or sucrose (see below, section "Important information about some of the ingredients of Dulcolax").
- by children under 2 years of age.

You should not take Dulcolax if you have a disease associated with a disturbed water and electrolyte balance (e.g. severe dehydration).

Appropriate precautions for use; special warnings:

Warnings and precautions

Talk to your doctor or pharmacist before taking Dulcolax. Without medical investigation, laxatives should be used on a short-term basis only. If you suffer from chronic constipation you should ask your doctor for advice. Increased fluid loss can lead to dehydration. This may be harmful under certain circumstances (e.g. in really impaired patients or in elderly patients). In these cases, Dulcolax should be discontinued and only continued under medical supervision. Stimulant laxatives including Dulcolax do not help with weight loss. Patients have reported blood in the stools; these were generally described as mild and disappeared without further treatment. Dizziness or brief episodes of fainting (syncope) have been reported in patients who have taken Dulcolax. The details available for these cases suggest that the syncope events were probably due to the act of defecation itself, to pressing or to circulatory reactions to abdominal pain.

Children

Dulcolax should not be used in children under the age of 2 years.

Dulcolax should only be given to children on medical advice.

Other medicines and Dulcolax

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Neutralizing stomach medicines (antacids)

To ensure that the active substance of Dulcolax is not released prematurely, Dulcolax should not be taken together with neutralizing stomach medicines (antacids). If you need to take an antacid, take it at the earliest half an hour after taking Dulcolax.

Diuretics, adrenocortical hormones

The concomitant use of diuretics (water tablets) or adrenocortical hormones (corticosteroids) may increase the risk of electrolyte imbalance if excessive doses of Dulcolax are taken.

Cardiotonic drugs

The sensitivity to certain drugs used to improve cardiac function (cardiac glycosides) may be increased as a result of electrolyte imbalances due to excessive use.

Laxatives

The concomitant use of other laxatives may enhance the gastrointestinal side effects of Dulcolax.

Dulcolax with food, drink and alcohol

Dulcolax should not be taken at the same time as milk to prevent the active substance from being released too early.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Since the introduction of Dulcolax in 1952, there have been no reports of undesirable or damaging effects during pregnancy. Studies on the use during pregnancy have not been carried out. Therefore, as with all medicines, Dulcolax should only be taken during pregnancy after you have consulted your doctor.

Breast-feeding

It has been shown that the active substance does not pass into breast milk. Dulcolax can therefore be used during lactation.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Please note that side effects are possible that could in theory impair your ability to drive or use machines.

Important information about some of the ingredients of Dulcolax

Each Dulcolax sugar-coated tablet contains approx. 35 mg lactose (milk sugar) and approx. 20 mg sucrose (sugar). If you have been told that you have an intolerance to some sugars, please consult your doctor before taking Dulcolax.

3. HOW TO TAKE DULCOLAX

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dose is as follows:

- for adults and children over 10 years: 1 - 2 Dulcolax sugar-coated tablets (equivalent to 5 - 10 mg bisacodyl) once in the evening;
- for children from 2 to 10 years: 1 Dulcolax sugar-coated tablet (equivalent to 5 mg bisacodyl) once in the evening.

It is recommended to start with the lowest dose level. The dose can be gradually adjusted to the maximum recommended dose to enable regular passing of stool. The maximum daily dose of 1 - 2 sugar-coated tablets (for adults and children over 10 years) and of 1 sugar-coated tablet (for children aged 2 to 10 years) should not be exceeded.

Swallow Dulcolax whole with sufficient liquid (preferably a glass of water, but not milk).

An evacuation is produced within approximately 6 - 12 hours.

To empty the bowel in preparation for treatments and measures to recognize diseases (therapeutic and diagnostic procedures) of the bowel and for diseases that call for an easier emptying of the bowel, take the medicine as instructed by your doctor.

Dulcolax is generally taken as a single treatment. In case of recurrent symptoms, Dulcolax can be taken again. Dulcolax should not be taken on a continuous daily basis or for long periods of time without investigating the cause of the constipation.

If you take more Dulcolax than you should

Overdose can lead to diarrhoea and abdominal cramps, with significant losses of fluid, potassium and other mineral salts. If your symptoms are severe, ask your doctor for advice.

Treatment should be guided by the predominant symptoms. If necessary, the water and salt losses (especially regarding potassium) have to be balanced.

Note:

It is generally known that chronic overdose with laxatives (e.g. Dulcolax) may cause chronic diarrhoea, abdominal pain, decreased potassium levels, excessive aldosterone secretion and kidney stones. Kidney damage, a metabolism-related increase in the alkalinity of the blood and muscle weakness due to decreased potassium levels have also been described in association with chronic laxative abuse.

If you forget to take Dulcolax

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

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

The most commonly reported undesirable effects during treatment are abdominal pain and diarrhoea.

The following categories are used to rank the undesirable effects by frequency of occurrence:

Very common: More than 1 in 10 patients
Common: Between 1 in 10 and 1 in 100 patients
Uncommon: Between 1 in 10 and 1 in 1,000 patients
Rare: Between 1 in 10 and 1 in 10,000 patients
Very rare: Fewer than 1 in 10,000 patients
Not known: Frequency cannot be estimated from the available data

Possible side effects

Immune system

Rare: Hypersensitivity reactions
Not known: Severe immediate allergic reaction, swelling of the skin and mucous membranes.

Metabolic disorders

Not known: Loss of water

Gastrointestinal tract

Common: Abdominal cramps, abdominal pain, diarrhoea, nausea

Uncommon: Vomiting, blood in the stool, abdominal discomfort, rectal discomfort

Not known: Inflammation of the colon (colitis) including colitis caused by hypoperfusion of the intestinal mucosa (schaemic colitis)

Nervous system

Uncommon: Dizziness

Not known: Brief loss of consciousness (syncope)

These events may be circulatory reactions due to constipation-related abdominal pain or the act of defecation itself (see also "Take special care with Dulcolax" in section 2).

Incorrect (prolonged and excessive) use of Dulcolax can cause losses of water, potassium and other electrolytes. This can lead to disorders of cardiac function and to muscle weakness, particularly if Dulcolax is used concomitantly with diuretics (water pills) or adrenocortical hormones (corticosteroids). The sensitivity to certain drugs used to improve cardiac function (cardiac glycosides) may be increased.

Reporting of side effects

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DULCOLAX

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the carton and on the container after EXP. The expiry date refers to the last day of that month. Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dulcolax sugar-coated tablets contains

The active substance is bisacodyl. Each gastro-resistant tablet (sugar-coated tablet) contains 5 mg bisacodyl.

The other ingredients are: acacia, carnauba wax, colouring agents (ferric oxide yellow (E172), titanium dioxide (E171)), eudragit L 100, eudragit S 100, glycerol, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, modified starch (oxidised maize starch), sucrose, talc, omanthum, castor oil, white beeswax, shellac.

What Dulcolax sugar-coated tablets look like and contents of the pack

Dulcolax contains the active substance bisacodyl, which has been proven to be effective for more than 60 years. Each Dulcolax coated tablet contains a special coating that only releases the active substance in the bowel – at the actual site of the constipation. Once released, bisacodyl stimulates the muscle actions of the bowel, thus loosening the constipation.

Not all pack sizes may be marketed in your country.

Marketing Authorization Holder

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Manufacturer

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Dear patient,

Nearly everyone suffers from constipation at some point in their life. The individual causes can be manifold. Below you will find some advice about constipation and about the treatment with Dulcolax.

What is constipation?

Everybody has their own intestinal rhythm: a bowel movement three times a week to three times a day is considered normal and regular.

Important: you do not have to have a bowel movement every day. From a medical point of view, the term constipation applies if one has a bowel movement less than three times per week, if strong pressing is required and/or if the stool has a hard and dry consistency. Constipated patients often feel like the bowel is not completely empty.

What are the causes of constipation?

Constipation develops when the normal muscle actions in the bowel slow down or are not strong enough to eliminate the digested food. This problem can have different causes:

- Hormonal influences or changes (e.g. pregnancy, imminent menstruation, menopause)
- Stress
- Changes in the nutrition and lifestyle habits (e.g. while travelling)
- Specific diseases (such as diabetes mellitus or Parkinson's disease)
- Certain medicines (such as antidepressants, strong painkillers, iron substitution products)
- Increasing age

How does Dulcolax actually work?

Dulcolax contains the active substance bisacodyl, which has been proven to be effective for more than 60 years. Each Dulcolax coated tablet contains a special coating that only releases the active substance in the bowel – at the actual site of the constipation. Once released, bisacodyl stimulates the muscle actions of the bowel, thus loosening the constipation.

Note:

Give your bowel some time to fill up again after taking Dulcolax. Depending on the composition and the quantity of food it may take a few days for your bowel to become so full that a normal bowel movement can be triggered. And remember: you do not have to have a bowel movement every day!

How do I find my personal Dulcolax dose?

- If you are taking Dulcolax for the first time, we recommend starting with one tablet.
- The correct Dulcolax dose that works best for you is the lowest dose required to obtain a soft and formed stool.
- For adults and children over 10 years: 1 - 2 Dulcolax sugar-coated tablets (equivalent to 5 - 10 mg bisacodyl) once For children from 2 to 10 years: 1 Dulcolax sugar-coated tablet (equivalent to 5 mg bisacodyl) once.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to an instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medication.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists