

DULCOLAX TABLET®

Bisacodyl (5mg)

What is in this leaflet

1. What DULCOLAX Tablet is used for
2. How DULCOLAX Tablet works
3. Before you use DULCOLAX Tablet
4. How to use DULCOLAX Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of DULCOLAX Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What DULCOLAX Tablet is used for DULCOLAX Tablets contain a medicine called bisacodyl. This belongs to a group of medicines called laxatives.

- DULCOLAX Tablets are used for relief of constipation. This medicine does not help with weight loss.
- DULCOLAX Tablets are also used in preparation of diagnostic procedures, in pre- and postoperative treatment and in conditions, which require defecation to be facilitated

How DULCOLAX Tablet works DULCOLAX Tablets are laxative that acts in stimulation of defecation, reduction of transit time, and softening of the stool. This specifically stimulates the natural evacuation process in the lower region of the gastrointestinal tract.

Before you use DULCOLAX Tablet

-When you must not use it, if:

- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product (listed in Product Description section)
- You are intolerant to or cannot digest some sugars (as the tablet

contains a small amount of lactose and sucrose)

- You have severe dehydration
- You have a bowel condition called “ileus” (blockage in the intestine)
- You have acute abdominal condition such as appendicitis
- You have severe abdominal pain with nausea and vomiting
- You have a blocked bowel (intestinal obstruction)
- You have inflammation of the bowel

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before using this medicine.

Pregnancy and lactation

Talk to your pharmacist or doctor before using DULCOLAX Tablets if you are pregnant or planning to become pregnant. DULCOLAX Tablets should not be taken in pregnancy and breast feeding unless the expected benefit is thought to outweigh any possible risk and as advised by your prescriber.

-Before you start to use it

Ask your pharmacist or doctor if you need more information or advice.

-Taking other medicines

Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines.

- Water tablets (diuretics) such as bendrofluazide or furosemide (frusemide)
- Steroid med medicines such as prednisolone
- Other laxative medicines

If you are not sure if any of the above applies to you, talk to your pharmacist or doctor before taking Dulcolax Tablet.

How to use DULCOLAX Tablets

-How much to use

For constipation:

Adults and children over 10 years

- Take one to two tablets (5 - 10 mg) daily before bedtime
- If you have not taken DULCOLAX Tablets before, start with one tablet and increase to two if necessary
- When your bowel regularity has returned to normal, the dose can usually be stopped

Children aged 4-10 years

DULCOLAX 5 mg Tablets should only be given to children between the ages of 4 and 10 if recommended by a doctor. The usual dose for children is one tablet (5 mg) daily before bedtime

Children under 4 years

DULCOLAX Tablets are not recommended for children under 4 years.

For preparation of diagnostic procedures and preoperatively:

This should be used under medical supervision.

Adults and children over 10 years:

Take two coated tablets in the morning and two coated tablets in the evening followed by one 10 mg suppository on the following morning.

Children aged 4 – 10 years:

Give one coated tablet in the evening and one 5 mg suppository on the following morning.

-When to use it

It is recommended to take the coated tablets at night to have a bowel movement the following morning. They should be swallowed whole with an adequate amount of fluid.

-How long to use it

These tablets should **not be used every day for more than 5 days**. If you need laxatives every day, then you should see

DULCOLAX TABLET®

Bisacodyl (5mg)

your doctor to find the cause of your constipation. Overuse can be harmful.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

-If you use too much (overdose)

If you take more Dulcolax Tablet 5mg than you should

It may be harmful to

- Take too many Dulcolax Tablet 5mg or
- Take Dulcolax Tablet 5mg for too long

This is because taking too many for too long may lead to:

- Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.
- Low levels of potassium in the blood (called 'hypokalaemia'). This can make you tired, dizzy, make your muscles weak and cause an uneven heart-beat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you; this is so the doctor knows what you have taken.

If you have any questions on the use of this product, ask your pharmacist or doctor.

While you are using it

-Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are using DULCOLAX Tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give DULCOLAX Tablets to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Milk, antacids or proton pump inhibitors (medicines which reduce acidity of the upper gastrointestinal tract) should not be taken together with DULCOLAX Tablets. This is because it will prematurely dissolve the enteric coating.

The tablets contain a small amount of lactose and sucrose in each tablet. Patients with rare hereditary problems of fructose intolerance, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption or sucraseisomaltase insufficiency should not use this medicine.

If you have an intolerance to some sugars, contact your doctor before taking this medicine.

Driving and using machines

Some people may feel dizziness and/or fainting while taking this medicine. If this happens to you, wait until these feelings go away before driving or using machines.

Side effects

Like all medicines, DULCOLAX Tablets can cause side effects, although not everybody gets them. If you experience any of the following side effects, please stop taking the medicines and see your doctor straight away:

Rare side effects (affect less than 1 in 1000 people)

- Severe allergic reactions which may cause swelling of the face or throat and difficulty in breathing or dizziness. If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away.
- Colitis (inflammation of the large intestine which causes abdominal pain and diarrhoea)
- Dehydration

- Allergic reactions which may cause a skin rash

- Fainting

Uncommon side effects (affect less than 1 in 100 people)

- Blood in the stools
- Vomiting
- Abdominal discomfort
- Discomfort inside and around the back passage
- Dizziness

Common side effects (affect less than 1 in 10 people)

- Abdominal cramps or pain
- Diarrhoea
- Nausea

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

By reporting side effects you can help provide more information on the safety of this medicine.

Storage and Disposal of DULCOLAX Tablets

-Storage

Store below 30°C.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

DULCOLAX Tablets are round, beige yellow biconvex, sugar/enteric-coated tablets with a smooth, shiny surface and a white core. They are

DULCOLAX TABLET®

Bisacodyl (5mg)

available in packs of 30 or 200
tablets per box. Not all pack sizes
may be marketed.

-Ingredients

-Active ingredient(s):
Bisacodyl 5mg

-Inactive ingredients:

Lactose monohydrate, maize
starch, sucrose, glycerol,
magnesium stearate, talc, acacia
(powdered), white beeswax,
shellac, carnauba wax, titanium
dioxide, yellow iron oxide,
methacrylic acid-methyl
methacrylate copolymer, soluble
starch, castor oil and macrogol
6000

-MAL number(s):

MAL09020985XCZ

Manufacturer

Delpharm Reims
Reims, France

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm,
No. 1, Jalan SS7/26A, Kelana
Jaya 47301 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Date of revision

20/05/2025

Serial Number

NPRA(R2/2)231023/1162