

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dulcolax

5 mg, film-coated tablets

BISACODYL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What DULCOLAX is and what it is used for
2. Before you take DULCOLAX
3. How to take use DULCOLAX
4. Possible side effects
5. How to store DULCOLAX
6. Further information

1. WHAT DULCOLAX IS AND WHAT IT 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
- DULCOLAX Tablets can also be used in a hospital to empty a person's bowel before child birth, surgery or radiological investigations.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is "normal and regular" varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

- Constipation is an occasional problem for some people. For others, it may happen more often.
- It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body.

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet

- A diet with not enough fiber
- Loss of 'tone' of the bowel muscles in older people
- Pregnancy
- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally "off color". Sometimes it causes headaches. These healthy tips are recommended to try to prevent constipation happening:

- Eat a balanced diet including fresh fruit and vegetables
- Drink enough water so that you do not become dehydrated
- Keep up your exercise and stay fit
- Make time to empty your bowels when your body tells you

2. BEFORE YOU TAKE DULCOLAX

Do not take DULCOLAX

- You are allergic (hypersensitive) to bisacodyl or any of the other ingredients in the product (listed in Section 6: Further information)
- 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 a serious 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 (small or large intestine)

Take special care with DULCOLAX

Check with your doctor or pharmacist before taking your medicine if:

- If you constantly need laxatives (medicines for bowel movements), every day or for longer periods • you should contact your doctor to examine the causes of constipation because prolonged excessive use can lead to an imbalance of fluids and electrolytes, and thus to reduced concentration of potassium in the blood.
- If you notice that you're thirsty or if you produce reduced amount of urine, which may be the result of dehydration due to fluid loss and can be dangerous for the elderly or patients with kidney disease • you should stop taking Dulcolax and contact your doctor.

If you notice blood in the stool you should contact your doctor.

Patients taking Dulcolax can sometimes experience dizziness and / or short-term loss of consciousness. These events may be associated with constipation (strain during bowel movements, abdominal pain), and not with taking the medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Dulcolax Tablets can affect the way some other medicines work. Also some other medicines can affect the way Dulcolax Tablets work.

The concomitant use of diuretics (water tablets) or corticosteroids (such as prednisone) may increase the risk of electrolyte imbalance if you take them with excessive doses of Dulcolax.

The imbalance of electrolytes can lead to increased sensitivity to cardiac glycosides (group of medicines used in the treatment of heart failure and irregular heartbeat, eg, digoxin).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Talk to your pharmacist or doctor before taking DULCOLAX Tablets if you are pregnant, planning to become pregnant or are breast feeding.

Driving and using machines

The studies about the effects on the ability to drive and use machines have not been conducted. However, some people may feel dizzy or faint while taking this medicine. If this happens to you, wait until these feelings go away before driving or using machines.

3. HOW TO TAKE DULCOLAX

Dulcolax is used in adults and children older than 10 years.

Always use 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.

DULCOLAX Tablets should not be taken every day for more than five days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

The usual dose is:

For constipation

Adults and children over 10 years: 1-2 tablets (5-10 mg) before bedtime

Children aged 4-10 years: 1 tablet (5 mg) before bedtime

DULCOLAX Tablets should only be given to children between the ages of 4 and 10 if recommended by a doctor.

DULCOLAX Tablets are not recommended for children under 4 years.

Milk, antacids or proton pump inhibitors (medicines which reduce stomach acid) should not be taken within one hour before or after taking DULCOLAX Tablets. This is because they will stop the DULCOLAX Tablets from working properly.

If you take more DULCOLAX than you should

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 forget to take DULCOLAX

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

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

If you stop taking DULCOLAX

Dulcolax should be used only when necessary and the treatment should be discontinued after the relief of symptoms.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

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
- Diarrhea
- Nausea

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DULCOLAX

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use DULCOLAX after the expiry date which is stated on the label, 3 years from the date of manufacture.

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

6. FURTHER INFORMATION

What DULCOLAX contains

Each tablet contains 5 mg of bisacodyl as the active ingredient

- The other ingredients are: lactose monohydrate, maize starch, sucrose (approximately 21 mg per tablet), glycerol, magnesium stearate, talc (E553b), acacia (powdered), white beeswax (E901), shellac (E904), carnauba wax (E903), titanium dioxide (E171), yellow iron oxide (E172), methacrylic acid-methyl methacrylate copolymer, castor oil and macrogol 6000

What DULCOLAX looks like and contents of the pack

Dark yellow, round, biconvex tablets coated with a smooth glossy surface 20 coated tablets PVC / PVDC / blister

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Delpharm Reims
10 rue Colonel Charbonneaux
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