

Dulcolax[®]

10 mg SUPPOSITORIES
and
5 mg SUPPOSITORIES
FOR CHILDREN
bisacodyl



Patient Information Leaflet: Information for the user

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. You need to use DULCOLAX Suppositories as instructed in this leaflet to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact your pharmacist or doctor if your symptoms worsen or do not improve after 5 days of treatment
- If a side effect occurs and gets troublesome, or seems serious to you, or if you experience any side effect not listed in this leaflet, please tell your pharmacist or doctor

In this leaflet:

1. What DULCOLAX Suppositories are and what they are used for
2. Before you use DULCOLAX Suppositories
3. How to use DULCOLAX Suppositories
4. Possible side effects
5. How to store DULCOLAX Suppositories
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1. WHAT DULCOLAX SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

DULCOLAX Suppositories contain a medicine called bisacodyl. This belongs to a group of medicines called laxatives.

- DULCOLAX Suppositories are used for relief of constipation
- This medicine does not help with weight loss
- DULCOLAX Suppositories are also used in hospitals to clear the bowel before surgery, X-rays or other tests
- DULCOLAX Suppositories stimulate the muscles of the bowel (large intestine), helping to return the body to its natural rhythm. They have a laxative effect usually within 10 to 30 minutes

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 the 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 fibre
- 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 is uncomfortable. It may make you feel bloated and heavy, or generally "off colour". Sometimes it causes headaches.

These healthy tips are recommended to try and 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 USE DULCOLAX SUPPOSITORIES

Do not use DULCOLAX Suppositories if:

- You are allergic (hypersensitive) to bisacodyl or hard fat
- 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)
- You have cracking of the skin around your back passage (anal fissures)
- You have inflammation or ulcers around your back passage (ulcerative proctitis)

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

Taking other medicines

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

In particular, tell your pharmacist or doctor if you are taking any of the following medicines:

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

Before using DULCOLAX Suppositories, tell your pharmacist or doctor if you are not sure if any of the above applies to you.

Pregnancy and breast-feeding

Talk to your pharmacist or doctor before using DULCOLAX Suppositories if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines

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 USE DULCOLAX SUPPOSITORIES

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or if you are not sure, ask your pharmacist or doctor.

As with all laxatives, DULCOLAX Suppositories should not be used every day for more than 5 days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

How to use the suppositories

The suppositories should only be used in your back passage.

1. Take off the foil wrapping
2. Lie on one side and pull your knees up towards your chest. Keep one leg drawn up more than the other
3. Use your first finger (index finger) or middle finger to push in the suppository
4. Gently push the suppository as far as possible into your back passage, pointed end first
5. Once it is as far as it will go, push it side-ways to make sure it touches the wall of the bowel
6. Lower your legs to a comfortable position whilst the suppository is retained in place
7. Keep the suppository inside you for at least 30 minutes

If you feel the suppository might come out straight away:

- You may not have put it in high enough. Push it in as far as possible
- Try to keep it in for 30 minutes, even if you feel like you urgently need to go to the toilet. This is how long it takes to work

How much to use

For constipation

Adults and children over 10 years

- Put one 10 mg suppository into the back passage for immediate effect. Only use one suppository per day

Children under 10 years

- DULCOLAX 5 mg Suppositories for Children should only be used if recommended by a doctor. The usual dose is:
- Put one 5 mg suppository into the back passage for immediate effect. Only use one suppository per day

Children under 4 years

Do not use in children under 4 years of age

For bowel clearance before surgery, X-rays or other tests In hospitals, when patients are being prepared for surgery, X-rays or other tests, DULCOLAX Suppositories and DULCOLAX Tablets are both used. This helps to get complete bowel clearance.

Adults and children over 10 years

- Take two tablets in the morning and two tablets in the evening and use one 10 mg suppository on the following morning

Children 4 -10 years

- Give one tablet in the evening and one 5 mg suppository (DULCOLAX 5 mg Suppositories for Children) on the following morning

Children under 4 years

Do not use in children under 4 years of age

If you use too many DULCOLAX Suppositories

It may be harmful to

- Use too many DULCOLAX Suppositories or
 - Use DULCOLAX Suppositories for too long
- This is because using 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 use more DULCOLAX Suppositories than you should If you use 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DULCOLAX Suppositories can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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

Reporting of side effects

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 can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adportal

5. HOW TO STORE DULCOLAX SUPPOSITORIES

- Keep this medicine out of the sight and reach of children
- Do not use DULCOLAX Suppositories after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C
- The suppositories should be protected from light. Keep them in the outer carton
- 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 protect the environment

6. FURTHER INFORMATION

What DULCOLAX Suppositories contain

- DULCOLAX 10 mg Suppositories contain 10 mg of the active ingredient bisacodyl
- DULCOLAX 5 mg Suppositories for Children contain 5 mg of the active ingredient bisacodyl
- Both the suppositories are made from hard fat, which is an ingredient needed to mould the suppository into the correct shape

What DULCOLAX Suppositories look like and contents of the pack

- The suppositories are white and torpedo shaped
- DULCOLAX 10 mg Suppositories are available in packs of 10, 12 and 20. Not all pack sizes may be marketed
- DULCOLAX 5 mg Suppositories for Children are available in packs of 5

Marketing Authorisations are held by:

Ireland
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DULCOLAX Suppositories are manufactured by:

Istituto De Angeli S.r.l., Località Prulli n. 103/c
50066 Reggello (FI), Italy.

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