

Dulcolax[®]

Twelve Plus

10 mg SUPPOSITORIES

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.

What is in this leaflet:

1. What Dulcolax Twelve Plus Suppositories are and what they are used for
2. What you need to know before you use Dulcolax Twelve Plus Suppositories
3. How to use Dulcolax Twelve Plus Suppositories
4. Possible side effects
5. How to store Dulcolax Twelve Plus Suppositories
6. Contents of the pack and other information

1. What Dulcolax Twelve Plus Suppositories are and what they are used for.

Dulcolax Twelve Plus Suppositories are used for the short-term relief of occasional constipation. Dulcolax Twelve Plus Suppositories contain bisacodyl which belongs to a group of medicines known as stimulant laxatives, which increase bowel movements. This medicine does not help with weight loss.

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
- Not drinking enough fluids
- 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.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using this medicine.

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. What you need to know before you use Dulcolax Twelve Plus Suppositories

Do not use Dulcolax Twelve Plus 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 take this medicine if any of the above applies to you. Do not use in children under the age of 12 years. If you are not sure, talk to your pharmacist or doctor before using this medicine.

Does this help with weight loss?

Stimulant laxatives (including Dulcolax Twelve Plus Suppositories) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your health by:

- Causing disturbances of electrolyte and mineral balances. Sodium, potassium, magnesium, and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles, including those of the colon and heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- Severe dehydration may cause tremors, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration often requires medical treatment.
- Overuse of laxatives must be avoided as it may harm the intestinal function

Other medicines and Dulcolax Twelve Plus Suppositories

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Dulcolax Twelve Plus Suppositories can affect the way some other medicines work. Also, some other medicines can affect the way Dulcolax Twelve Plus Suppositories work.

In particular, tell your doctor or pharmacist if you are taking:

- Water tablets (diuretics) such as bendrofluzide or furosemide (frusemide)
- Steroid 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 using Dulcolax Twelve Plus Suppositories.

Pregnancy and breast-feeding

Talk to your pharmacist or doctor before using Dulcolax Twelve Plus 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 Twelve Plus Suppositories

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

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 Twelve Plus 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

Adults and children 12 years and over:

Put one 10 mg suppository into the back passage for immediate effect (they usually have a laxative effect within 10 to 30 minutes). Only use one suppository per day. This should not be used in children or adolescents under the age of 12 years.

Length of treatment

These suppositories should not be used every day for more than 5 days. If you need laxatives every day, then you should see your doctor to find the cause of your constipation. Overuse can be harmful.

If you use more Dulcolax Twelve Plus Suppositories than you should

It may be harmful to:

- Use too many Dulcolax Twelve Plus Suppositories
 - Use Dulcolax Twelve Plus Suppositories for too long
- This is because using too much 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 heartbeat.
 - Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

4. Possible side effects

Like all medicines, Dulcolax Twelve Plus Suppositories can cause side effects, although not everybody gets them. If you experience any of the following side effects, please stop using 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

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dulcolax Twelve Plus Suppositories

- Keep this medicine out of the sight and reach of children
- Do not use Dulcolax Twelve Plus 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
- Keep the blister within the outer carton to protect from light
- 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 protect the environment.

6. Contents of the pack and other information

What Dulcolax Twelve Plus Suppositories contain

- Dulcolax Twelve Plus 10 mg Suppositories contain 10 mg of the active ingredient bisacodyl
- The suppositories are made from hard fat, which is an ingredient needed to mould the suppository into the correct shape

What your suppositories look like and the contents of the pack

Dulcolax Twelve Plus 10 mg Suppositories are packed in cartons containing blister strips. The cartons contain 10 or 12 suppositories. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, United Kingdom.

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Dulcolax Twelve Plus Suppositories are manufactured by:

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

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