sanofi

Dulcolax® 5 mg Suppositories & Dulcolax® 10 mg Suppositories

bisacodyl

Read all of this leaflet carefully before you start using 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

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 Suppositories is and what it is used for
- What you need to know before you use Dulcolax Suppositories
 How to use Dulcolax Suppositories
- 4. Possible side effects
- 5. How to store Dulcolax Suppositories 6. Contents of the pack and other information
- 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 to treat constipation
- Dulcolax Suppositories are also used to clear the bowel before surgery, X-rays or other tests
- Dulcolax Suppositories stimulate the muscles of the bowel (large intestine). They have a laxative effect usually within 10 to 30 minutes
- 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.

These healthy tips are recommended to try and prevent constipation happening:

- · Eat a balanced diet including fresh fruit and
- 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 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.

Other medicines and Dulcolax

Suppositories

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 doctor or

- pharmacist if you are taking: Water tablets (diuretics) such as bendrofluazide
- 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 using taking Dulcolax Suppositories.

Pregnancy and breast feeding

Talk to you pharmacist or doctor before using Dulcolax Suppositories if you are pregnant, planning to become pregnant or are breast

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

3. How to use Dulcolax **Suppositories**

Always use this medicine exactly as your doctor has told you. Otherwise, follow the instructions below. If you do not understand the instructions, or if you are not sure, ask your pharmacist or

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 minal 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
- 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 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

The recommended dose is:

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

 Put one 5 mg suppository into the back passage for immediate effect. Only use one suppository per day

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) on the following morning

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 course of your condition. find the cause of your constipation. Overuse can

If you use too many Dulcolax Suppositories than you should

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, 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 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. 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

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

- Abdominal cramps or pain
- Diarrhoea

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 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
- 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 Suppositories contain

- Dulcolax 10 mg Suppositories contain 10 mg of the active ingredient bisacodyl
- Dulcolax 5 mg Suppositories 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 6, 10, 12, 20, 50 and 200. Dulcolax 5 mg Suppositories are available in packs of 5, 6, 48 and 50. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, United Kingdom. Tel: 0800 035 2525

Email: uk-medicalinformation@sanofi.com **Dulcolax Suppositories are manufactured by:**

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

This leaflet was revised in December 2022. ® Registered trade mark 439186/GB/3