DULCOLAX® suppositories

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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DULCOLAX® 10 mg suppositories

DULCOLAX® 5 mg suppositories

Bisacodyl.

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

DULCOLAX® suppositories is available without a doctor's prescription, for you or your child to treat a mild illness. Nevertheless, you still need to use DULCOLAX® suppositories carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DULCOLAX® suppositories with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your or your child's symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What DULCOLAX® suppositories is and what it is used for.
2. What you need to know before you use DULCOLAX® suppositories.
3. 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 is and what it is used for

DULCOLAX® suppositories contain bisacodyl and belong to a group of medicines known as stimulant laxatives, which increase bowel movements. DULCOLAX® suppositories are used for short-term relief of occasional constipation.

DULCOLAX® suppositories does not help with weight loss.

2. What you need to know before you use DULCOLAX® suppositories

Do not use DULCOLAX® suppositories:

- if you or your child are hypersensitive (allergic) to bisacodyl or any of the other ingredients of DULCOLAX® suppositories (see section 6),
- if you or your child have a bowel condition called ileus (causing a blockage in your intestine),
- if you or your child suffer from a blocked bowel (intestinal obstruction),
- if you or your child have a serious abdominal condition, such as appendicitis,
- if you or your child suffer from inflammation of the bowel (small or large intestine),
- if you or your child have severe abdominal pain with nausea and vomiting,
- if you or your child are severely dehydrated,
- if you have cracking of the skin around your back passage (anal fissures),
- if you have inflammation or ulcers around your back passage (ulcerative proctitis).

Warnings and precautions

Take special care with DULCOLAX® suppositories:

- if you or your child suffer from chronic constipation. DULCOLAX® suppositories should not be taken for longer than 7 days,
- if you or your child have noticed a sudden change in your bowel habits that has persisted for a period of greater than 2 weeks, consult a doctor before using DULCOLAX® suppositories,
- if you or your child have kidney problems,
- if you are elderly,

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It is recommended to make changes in your or your child's diet and use bulk forming medicines to control constipation before using DULCOLAX® suppositories. 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.

If you or your child experience any rectal bleeding, bloody stools or you do not have a bowel movement after using DULCOLAX® suppositories, stop using DULCOLAX® suppositories and contact your doctor.

DULCOLAX® suppositories does not help with weight loss. It does not reduce the absorption of calories or nutrients. It can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives, such as DULCOLAX® suppositories, may damage your or your child's 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 your heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs in your body;
- 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 of your body.

Children and adolescents

DULCOLAX® suppositories should not be given to children without medical advice.

Other medicines and DULCOLAX® suppositories

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- diuretic medicines (used to treat high blood pressure or help eliminate excess water and salt from the body),
- steroid medicines (used to treat inflammation),
- cardio glycosides (used to treat heart failure or irregular heart beats),
- other laxatives (used to treat constipation).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using DULCOLAX® suppositories.

Safety and efficacy of DULCOLAX® suppositories during pregnancy and lactation have not been established.

Driving and using machines

DULCOLAX® suppositories can cause side effects such as dizziness or fainting. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how DULCOLAX® suppositories affects you.

3. How to use DULCOLAX® suppositories

Do not share medicines with any other person.

Bowel movement is generally produced within 15 minutes to one hour.

Adults and children 12 years and over:

The usual dose is one 10 mg suppository as a single daily dose.

Children 1 years to 12 years:

The usual dose is one 5 mg suppository as a single daily dose.

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.

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.

Do not exceed the recommended dosage. Always use DULCOLAX® suppositories 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.

If you have the impression that the effect of DULCOLAX® suppositories is too strong or too weak, tell your doctor or pharmacist.

If you use more DULCOLAX® suppositories than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining DULCOLAX® suppositories with you so the doctor will know what you have taken.

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If you forget to use DULCOLAX® suppositories

DULCOLAX® suppositories should only be used when you or your child are constipated. It should not be used for more than 7 days. Do not take a double dose.

4. Possible side effects

DULCOLAX® suppositories can have side effects.

Not all side effects reported for DULCOLAX® suppositories are included in this leaflet. Should your or your child's general health worsen or if you experience any untoward effects while using DULCOLAX® suppositories, please consult your health care provider for advice.

If any of the following happens, stop using DULCOLAX® suppositories and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to DULCOLAX® suppositories. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Side effect occurring less frequently:

- dehydration (increased thirst, feeling faint, headaches, passing less urine than normal).

This is a serious side effect. You or your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- cramps or pain of your stomach area,

- diarrhoea, nausea.

Side effects occurring less frequently:

- dizziness,
- blood in your stools, vomiting, discomfort of your stomach area, anal discomfort (discomfort inside or around your back passage), inflammation of your bowels (stomach pain or diarrhoea).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you or your child get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256-3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of DULCOLAX® suppositories.

5. How to store DULCOLAX® suppositories

- Store at or below 25 °C.
- Keep in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container/label/ carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DULCOLAX® suppositories contains

Each adult suppository contains bisacodyl 10 mg.

Each paediatric suppository contains bisacodyl 5 mg.

The other ingredient is hard fat Witepsol W 45.

What DULCOLAX® suppositories looks like and contents of the pack

DULCOLAX® 5 mg suppositories and DULCOLAX® 10 mg suppositories are smooth, white or slightly yellow, torpedo-shaped suppositories.

Aluminium foil blisters with the name printed on the foil, packed in an outer carton.

Pack size: 10 suppositories.

Holder of certificate of registration

sanofi-aventis south africa (pty) ltd.

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