DULCOLAX®

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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Dulcolax® 5 mg tablets

Bisacodyl.

Contains sugar: Each tablet contains 33,2 mg lactose monohydrate and 23,4 mg sucrose.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share DULCOLAX® 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® is and what it is used for.
2. What you need to know before you take DULCOLAX®.
3. How to take DULCOLAX®.
4. Possible side effects.
5. How to store DULCOLAX®.
6. Contents of the pack and other information.

1. What DULCOLAX® is and what it is used for

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

DULCOLAX® does not help with weight loss.

2. What you need to know before you take DULCOLAX®

Do not take DULCOLAX®:

- if you or your child are hypersensitive (allergic) to bisacodyl or any of the other ingredients of DULCOLAX® (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.

Warnings and precautions

Take special care with DULCOLAX®:

- if you or your child suffer from chronic constipation. DULCOLAX® 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®,
- if you or your child have kidney problems,
- if you are elderly,

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

DULCOLAX® 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®, 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® should not be given to children under the age of 6 years.

Other medicines and DULCOLAX®

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:

- antacids (used for indigestion or heartburn). Do not take DULCOLAX within 1 hour after taking an antacid,

- 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).

DULCOLAX® with food, drink and alcohol

Do not take DULCOLAX® within one hour after taking milk.

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 taking DULCOLAX®.

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

Driving and using machines

DULCOLAX® 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® affects you.

DULCOLAX® contains lactose and sucrose

If you or your child have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking DULCOLAX®.

3. How to take DULCOLAX®

Do not share medicines with any other person.

Bowel movement is generally produced within 6 to 12 hours.

Adults and children 12 years and over:

The usual dose is 1 – 3 tablets as a single daily dose.

Children 6 years to under 12 years:

The usual dose is 1 tablet daily.

The tablets should be swallowed whole with adequate fluid.

The tablets should be taken at night to produce evacuation the following morning.

Do not exceed the recommended dosage. Always take DULCOLAX® 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® is too strong or too weak, tell your doctor or pharmacist.

If you take more DULCOLAX® 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® with you so the doctor will know what you have taken.

If you forget to take DULCOLAX®

DULCOLAX® 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® can have side effects.

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

If any of the following happens, stop taking DULCOLAX® 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®. 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®.

5. How to store DULCOLAX®

- Store at or below 30 °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® contains

Each enteric coated tablet contains bisacodyl 5 mg.

The other ingredients are:

Tablet core:

Glycerol (E422), lactose monohydrate, magnesium stearate (E572), maize starch, and soluble starch.

*Tablet coating**:***

Acacia, carnauba wax (E903), castor oil (E1503), macrogol 6000 (E1521), magnesium stearate (E572), methacrylic acid-methylmethacrylate copolymer (1:1), methacrylic acid-methylmethacrylate copolymer (1:2), shellac (E904), sucrose, talc (E553b), titanium dioxide (E171), white beeswax (E901), yellow iron oxide (E172).

What DULCOLAX® looks like and contents of the pack

Round, beige-yellow, biconvex sugar/enteric coated tablets with a smooth, shiny surface and a white core.

Opaque white PVC/PVDC/silver aluminium foil blister packs of 4, 10, 30, 40, 60 and 200 tablets.

Holder of certificate of registration

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