Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dulcolax. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. If you have any concerns about taking this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this information with the medicine. You may need to read it again.

What Dulcolax is used for

Dulcolax is used to treat constipation.

Under medical supervision, Dulcolax can be used for the evacuation of the bowel before a radiological examination or as an enema alternative.

Dulcolax works by acting on the lining of the lower bowel to stimulate movement and promotes accumulation of water into the bowel to produce soft formed stools.

Dulcolax is ineffective in altering the digestion or absorption of calories in the small intestine and therefore does not assist with weight loss.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you use Dulcolax

When you must not use it

Do not use Dulcolax if you are allergic to:

- any medicine containing bisacodyl
- any of the ingredients listed at the end of this leaflet.

Do not use Dulcolax if you have or have had, any of the following conditions:

- acute abdominal conditions including appendicitis
- acute inflammatory bowel disease
- severe abdominal pain with nausea and vomiting
- blockage in the bowel (ileus)
- a blockage in the intestine
- severe dehydration.

If you are uncertain as to whether you have, or have had, any of these conditions, talk to your doctor or pharmacist.

Do not give this medicine to a child under the age of 10 years.

There is not enough information to recommend the use of this medicine for children under the age of 10 years.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor or pharmacist if you have, or have had, any other medical conditions including:

- an anal fissure (painful tear in the lining of the anus)
- ulcerative proctitis (inflammation of the rectum)

Suppositories may cause pain and local irritation, especially if you have a painful tear in the lining of the anus or inflammation of the rectum.

Tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

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

- diuretics (medicines that increase urine volume)
- corticosteroids
- medicines which stimulate the heart e.g. digoxin.

These medicines may be affected by Dulcolax or may affect how well it works. You may need different amounts of your medicines, or may need to take different medicines.

Use of Dulcolax with other laxatives may enhance gastrointestinal side effects.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Dulcolax does not pass into breast milk and can be used during breastfeeding.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start using Dulcolax.

How to use Dulcolax

Follow the directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to use

Dulcolax should be used in children only on medical advice. Dulcolax suppositories may be used in children 10 years of age and over.

The usual doses for adults and children over 10 years are stated below.

For Constipation

one suppository (10 mg) as needed.

If your doctor or pharmacist has changed the recommended dose, ask for further information from your doctor or pharmacist.

For Enema Alternative

Dulcolax should only be used under medical supervision.

- two Dulcolax tablets at night followed by one suppository (10 mg) the following morning or
- where the above is not possible, use two suppositories (2 x 10 mg).

If your doctor or pharmacist has changed the recommended dose, ask for further information from your doctor or pharmacist.

Before a Radiological examination

Dulcolax should only be used under medical supervision.

 two Dulcolax tablets on each of the two preceding nights, followed by one suppository (10 mg), 1¹/₂ hours before the actual procedure.

If your doctor or pharmacist has changed the recommended dose, ask for further information from your doctor or pharmacist.

How to use it

Follow the directions below to use Dulcolax suppositories:

- 1. Wash your hands thoroughly with soap and water.
- 2. Remove all of the foil wrapper from the suppository.
- 3. Lie on your side and raise your knee to your chest.
- 4. Push the suppository gently and slowly, pointed end first, into the rectum.
- 5. Throw away used materials and wash your hands thoroughly.

Dulcolax suppositories generally work in about 20 minutes, but may take up to 45 minutes.

If you are not sure how to use a suppository, ask your doctor or pharmacist for advice.

After taking Dulcolax, avoid straining while passing a bowel motion.

When to use it

Dulcolax should be used as needed to relieve constipation.

How long to use it

Dulcolax is recommended for short-term use only. If symptoms persist, seek medical advice.

Long-term use of Dulcolax is not recommended. If you use Dulcolax every day, you should consult with your doctor to find out the cause of your constipation. Long-term and excessive use may cause the bowel to become dependent on Dulcolax for

If you are not sure how long to use Dulcolax, talk to your doctor or pharmacist.

it to produce a bowel motion.

Long-term and excessive use of Dulcolax may cause an imbalance of salts in the body (including low potassium), muscle weakness, kidney problems and fluid imbalance. Loss of fluids from the body can cause dehydration. Symptoms of dehydration include thirst and passing less urine than normal. In patients experiencing fluid loss where dehydration may be harmful (for

example, kidney problems, elderly patients), Dulcolax should be stopped and only restarted under medical supervision.

If you use too much (overdose)

Seek medical advice immediately if you have used more than the recommended or prescribed dose of Dulcolax.

Advice can be provided by your doctor, pharmacist or Poisons Information Centre (telephone 13 11 26).

If you have taken too much Dulcolax, you may have diarrhoea, abdominal cramps, fluid loss, and an imbalance of salts in the body (including low potassium).

As with other laxatives, persistent overdose may cause diarrhoea, abdominal pain, imbalance of salts in the body (including low potassium), secondary hyperaldosteronism and kidney stones. If an imbalance of salts (low potassium) occurs, then kidney disease, metabolic alkalosis and muscle weakness may be experienced.

While you are using Dulcolax

Things to consider

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Dulcolax. Drink plenty of water while taking

laxatives.

An increase in fibre in your diet is recommended, except in cases of

medication-induced constipation.

Discuss with your doctor or pharmacist if you need to increase the fibre in your diet when using Dulcolax, to assist in the treatment of constipation.

Things to be careful of

Be careful driving or operating machinery until you know how Dulcolax affects you. Do not drive or operate machinery if you experience dizziness or fainting.

After using Dulcolax, avoid straining while passing a bowel motion.

Dizziness and fainting while straining have been reported in patients who have taken Dulcolax. It is not known if Dulcolax can cause dizziness or fainting.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Dulcolax.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- · colitis including ischaemic colitis
- abdominal discomfort
- · abdominal cramps
- abdominal pain
- nausea
- vomiting
- diarrhoea
- anorectal discomfort

- blood in the stool
- · dehydration
- dizziness
- fainting

Abdominal pain and diarrhoea are the most commonly reported side effects. These side effects are usually mild and short lived.

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

- · rash, itching or hives on the skin,
- swelling of the face, lips, tongue or other parts of the body,
- shortness of breath, wheezing or trouble breathing.

These are the symptoms of life-threatening allergic (anaphylactic) reactions.

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

After using Dulcolax

Storage

Keep Dulcolax in a cool dry place where the temperature stays below 25°C.

Do not store Dulcolax or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

Dulcolax suppositories containing 10 mg of bisacodyl are torpedo-shaped, smooth and white or slightly yellowish in colour. The suppositories are individually foil-wrapped and are available in packs of 10, 50* and 200* suppositories.

Dulcolax is also available as 5 mg tablets. Both Dulcolax tablets and Dulcolax suppositories are available from your local pharmacy without prescription.

* Pack sizes not distributed in Australia.

Inaredients

Dulcolax suppository contains 10 mg of bisacodyl as the active ingredient.

Inactive ingredient:

hard fat as the suppository base.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Dulcolax suppositories are supplied in Australia by:

Sanofi Consumer Healthcare, 87 Yarraman Place, Virginia, Qld 4014 Australia. Toll-free: 1800 818 806

Australian Registration Number

AUST R 17926

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