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 take Dulcolax

When you must not take it

Do not take Dulcolax if you are allergic to:

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

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

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

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 6 years.

Dulcolax should only be used in children over the age of 6 years on medical advice.

Do not take 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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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 taking Dulcolax.

How to take Dulcolax

Follow all 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 box, ask your doctor or pharmacist for help.

How to take it

Swallow Dulcolax tablets whole with a glass of water.

Do not crush or chew Dulcolax tablets.

Do not take Dulcolax tablets together with medicines that lower acidity of the upper gastrointestinal tract (stomach).

These medicines include antacids, and a group of medicines called proton pump inhibitors. If you think you may be taking any of these medicines, please speak with your doctor or pharmacist.

Do not take milk or antacids within 1 hour of taking Dulcolax tablets.

These may affect how well Dulcolax tablets work

Dulcolax tablets generally work in 6-12 hours

Recommended dose of Dulcolax for constipation

Dulcolax should be taken as needed to relieve constipation.

Adults and children over 10 years:

One or two Dulcolax tablets at night. It is recommended to start with the lowest dose. The dose may be adjusted up to the maximum recommended dose to produce regular stools. The maximum daily dose should not be exceeded.

Children 6 to 10 years:

One Dulcolax tablet at night. Children 6 to 10 years with chronic constipation should only be treated under medical supervision.

Recommended dose of Dulcolax as an enema alternative

Dulcolax should only be used as an enema alternative under medical supervision.

Adults and children over 10 years:

Two Dulcolax tablets at night followed by one standard Dulcolax suppository (10 mg) the following morning.

OR

Where the above is not possible, use two standard Dulcolax suppositories (2 x 10 mg).

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

Recommended dose of Dulcolax before a radiological examination

Dulcolax should only be used for radiological use under medical supervision.

Adults and children over 10 years:

Two Dulcolax tablets on each of the two preceding nights, followed by one standard Dulcolax suppository (10 mg) 1 $^{1}/_{2}$ hours before the actual procedure.

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

How long to take 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 take Dulcolax every day, you should consult with your doctor to find out the cause of your constipation.

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 take too much (overdose)

Seek medical advice immediately if you have taken 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 experience 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 taking Dulcolax

Things to consider

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking 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 taking 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 taking 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, mouth, 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 taking Dulcolax

Storage

Keep Dulcolax in a cool dry place where the temperature stays below 30°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

Heat and damp can destroy some medicines.

Keep it where 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 tablets are round, beige-yellow, biconvex sugar-enteric coated tablets with a smooth shiny surface and a white core.

Dulcolax tablets are available in blister packs of 10* (sample pack), 20, 30*, 50, 80, 100* and 200 tablets.

* Pack sizes not distributed in Australia. Dulcolax is also available as suppositories.

Both Dulcolax tablets and Dulcolax suppositories are available from your local pharmacy without a prescription.

Ingredients

Each Dulcolax tablet contains 5 mg of bisacodyl and the following inactive ingredients: lactose, maize starch, glycerol, magnesium stearate, sucrose, purified talc, acacia, titanium dioxide, methacrylic acid copolymer, castor oil, macrogol 6000, iron oxide yellow CI77492, white beeswax, carnauba wax, shellac and maize starch (soluble).

Supplier

Dulcolax tablets are supplied in Australia by:

Sanofi Consumer Healthcare, 87 Yarraman Place, Virginia, Old 4014 Australia.

Toll-free: 1800 818 806

Australian Registration Number AUST R 155405

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