

Dulcolax SP DROPS

Oral liquid

Sodium picosulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dulcolax SP Drops. 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 SP Drops is used for

Dulcolax SP Drops is used to treat constipation.

Dulcolax SP Drops 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.

Sodium picosulfate, the active ingredient in Dulcolax SP Drops, is ineffective in altering the digestion or absorption of calories in the

small intestine and therefore does not assist with weight loss.

Before you take Dulcolax SP Drops

When you must not take it

Do not take Dulcolax SP Drops if you are allergic to:

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

Do not take Dulcolax SP Drops 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
- symptoms of water and electrolyte disturbances such as fatigue, weakness, muscle cramps, thirst, dizziness and fainting
- fructose intolerance (as this medicine contains sorbitol).

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor or pharmacist.

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 or pharmacist.

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.

In some cases you should not take Dulcolax SP Drops if you are allergic to certain medicines.

Before taking Dulcolax SP Drops you must tell your doctor if you have, or have had, any of the following conditions:

- kidney problems
- heart problems
- dehydration.

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

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

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

Sodium picosulfate, the active ingredient in Dulcolax SP Drops, does not pass into breast milk, therefore Dulcolax SP Drops can be used while breast feeding.

Ask for your doctor's or pharmacist's advice before giving Dulcolax SP Drops to your child.

Your doctor or pharmacist will determine if this medicine is suitable for your child.

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 or fluid tablets (medicines that increase urine volume)
- corticosteroids
- medicines which stimulate the heart e.g. digoxin
- antibiotics (medicines which kill bacteria).

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

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

How to take Dulcolax SP Drops

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 pack, ask your doctor or pharmacist for help.

How to take it

Follow the directions for use carefully:

1. Remove protective cap from bottle.
2. Do not shake the bottle. To make the dropper function, hold the bottle with the dropper facing downwards and gently squeeze the bottle.
3. Take the recommended dose or as directed by your doctor or pharmacist.
4. Replace the protective cap after use.

Dulcolax SP Drops can be dripped onto a spoon and should then be taken immediately.

Dulcolax SP Drops can be added to a glass of water. Drink the entire contents of the glass immediately after Dulcolax SP Drops have been added.

Dulcolax SP Drops generally work in 6 to 12 hours.

Dulcolax SP Drops taken at night usually produce a bowel motion the following morning.

Recommended dose

Adults and children over 10 years:

Initially 10 drops (5 mg) at night. Increase up to 20 drops (10 mg) only if required.

Children 4 to 10 years:

Initially 5 drops (2.5 mg) at night. Increase up to 10 drops (5 mg) only if required.

The maximum recommended dose should not be exceeded.

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 SP Drops is recommended for short-term use only. If symptoms persist seek medical advice.

Long-term use of Dulcolax SP Drops is not recommended. If you take Dulcolax SP Drops every day you should consult with your

doctor to find out the cause of your constipation.

Long-term or excessive use of Dulcolax SP Drops may cause an imbalance of salts in your body including lowering potassium levels in the blood and an excessive loss of water from your body. It may also cause the bowel to become dependent on Dulcolax SP Drops to produce a bowel motion.

If you take too much (overdose)

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

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

Signs of overdose may include diarrhoea and abdominal cramps as well as other medical problems caused by a loss of salts and water from your body. Damage to the lining of the large bowel may also occur.

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 SP Drops

Things to consider

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

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 amount of fibre in your diet, to assist in the treatment of constipation.

Things to be careful of

Be careful driving or operating machinery until you know how Dulcolax SP Drops affects you.

Do not drive or operate machinery if you experience dizziness or fainting.

After taking Dulcolax SP Drops, 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 SP Drops 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 SP Drops.

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.

Side effects of Dulcolax SP Drops include:

- abdominal discomfort
- abdominal cramps
- abdominal pain
- diarrhoea
- vomiting
- nausea
- dizziness

- fainting.

Dulcolax SP Drops may also cause allergic (hypersensitivity) reactions such as:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- skin rashes including hives, blisters, red patches and itching.

If these occur, seek medical attention immediately.

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

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

After taking Dulcolax SP Drops

Storage

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

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

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

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 SP Drops is a clear, colourless to yellowish or slightly

yellowish-brown, slightly viscous solution.

Dulcolax SP Drops are available in bottles that contain 15* and 30 mL of solution.

Dulcolax SP Drops are available from your local pharmacy without a prescription.

*Pack size not distributed in Australia.

Ingredients

Each 1 mL (approximately 15 drops) of Dulcolax SP Drops contains 7.5 mg of sodium picosulfate and the following ingredients:

- sodium benzoate
- sodium citrate
- citric acid monohydrate
- sorbitol solution (70%) (non-crystallising) and
- purified water.

Supplier

Dulcolax SP Drops are supplied in Australia by:

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308
78 Waterloo Road
NORTH RYDE NSW 2113

Australian Registration Number

AUST R 133243



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