

Package leaflet: Information for the user

Dulcolax® Pico Liquid 5mg/5ml oral solution (sodium picosulfate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. Always take Dulcolax Pico Liquid exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after five days.

What is in this leaflet:

1. What Dulcolax Pico Liquid is and what it is used for
2. What you need to know before you take Dulcolax Pico Liquid
3. How to take Dulcolax Pico Liquid
4. Possible side effects
5. How to store Dulcolax Pico Liquid
6. Contents of the pack and other information

1. What Dulcolax Pico Liquid is and what it is used for

Dulcolax Pico Liquid contains a medicine called sodium picosulfate. This belongs to a group of medicines called laxatives.

Dulcolax Pico Liquid is used for relief of constipation. This medicine does not help with weight loss. Dulcolax Pico Liquid gently stimulates the muscles of the bowel (large intestine). This brings predictable, overnight relief from constipation, helping to return the body to its natural rhythm.

What is constipation?

Normal and regular bowel movement is important for most people. However, what is “normal and regular” varies from person to person. Some may have a bowel movement every day, others less often. Whatever it is like for you, it is best that your bowel movement has a regular pattern.

- Constipation is an occasional problem for some people. For others, it may happen more often
- It happens when the normal muscle actions in the bowel (large intestine) slow down. This can mean that material is not easily eliminated from the body

The cause of constipation is often not known. It can be associated with:

- Sudden change of diet
- A diet with not enough fibre
- Loss of ‘tone’ of the bowel muscles in older people
- Pregnancy

- Medicines such as morphine or codeine
- Having to stay in bed for a long time
- Lack of exercise

Whatever the cause, constipation can be uncomfortable. It may make you feel bloated and heavy or generally “off colour”. Sometimes it causes headaches.

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

2. What you need to know before you take Dulcolax Pico Liquid

Do not take Dulcolax Pico Liquid if:

- You are allergic (hypersensitive) to sodium picosulfate or any of the other ingredients of this medicine (listed in Section 6)
- You have severe dehydration
- You have a bowel condition called “ileus” (blockage in the intestine)
- You have a serious abdominal condition such as appendicitis
- You have severe abdominal pain with nausea and vomiting and/or fever
- You have a blocked bowel (intestinal obstruction)
- You have inflammation of the bowel (small and large intestine)

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine.

Dulcolax Pico Liquid should not be taken for more than 5 days.

Prolonged excessive use may lead to fluid and electrolyte imbalance and hypokalaemia.

This medicine may cause abdominal spasm, dizziness and/or syncope (feeling faint).

Children and adolescents

Dulcolax Pico Liquid should not be taken by children under 10 years without medical advice.

Other medicines and Dulcolax Pico Liquid

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Dulcolax Pico Liquid can affect the way some other medicines work. Also, some other medicines can affect the way Dulcolax Pico Liquid works.

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

- Water tablets (diuretics) such as bendrofluzide or furosemide (frusemide)
- Steroid medicines such as prednisolone
- Antibiotics – used for infections

If you are not sure if any of the above applies to you, talk to your pharmacist or doctor before taking Dulcolax Pico Liquid.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you experience abdominal spasm, dizziness and/or syncope (feeling faint) you should avoid potentially hazardous tasks such as driving or operating machinery.

Important information about some of the ingredients in Dulcolax Pico Liquid

This medicine contains 480 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 4.8 w/v%. The amount in each 10 ml dose of this medicine is equivalent to less than 10.4 ml beer or 4.3 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

Dulcolax Pico Liquid contains the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate. These ingredients may cause allergic reactions (possibly delayed). The signs may include: a rash, swelling of your skin, mouth and face which may cause swallowing or breathing problems.

This medicine contains less than 1 mmol sodium (23 mg) per 10ml dose, that is to say essentially 'sodium-free'.

3. How to take Dulcolax Pico Liquid

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

As with all laxatives, Dulcolax Pico Liquid should not be taken for more than 5 days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

The recommended dose is

Adults and children over 10 years

- One to two 5 ml spoonfuls at night
- When your bowel regularity has returned to normal, the dose can usually be stopped

Children aged between 4 and 10 years

Dulcolax Pico Liquid should only be given to children under 10 if recommended by a doctor.

The usual dose for a child is:

- Half to one 5 ml spoonful at night

Children under 4 years

The dose will depend on the weight of your child: 0.25 ml for each kilogram of the child's body weight.

If you take more Dulcolax Pico Liquid than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you; this is so the doctor knows what you have taken.

If you have any questions on the use of this product, ask your pharmacist or doctor.

4. Possible side effects

Like all medicines, Dulcolax Pico Liquid can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Isolated events (some side effects are so rare that it is not known how many people may be affected)

- Syncope (feeling faint)
- Allergic reaction
- Skin reactions (rash, itching)

If you have a severe allergic reaction, stop taking this medicine and see a doctor straight away. The signs may include: a rash, swelling of your skin, mouth and face which may cause swallowing or breathing problems.

Very common side effects (affects 1 in 10 people or more)

- Diarrhoea

Common side effects (affects less than 1 in 10 people)

- Abdominal discomfort, cramps or pain

Uncommon side effects (affects less than 1 in 100 people)

- Nausea
- Vomiting
- Dizziness

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Dulcolax Pico Liquid

Keep this medicine out of the sight and reach of children.

Do not take Dulcolax Pico Liquid after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Keep the bottle within the outer carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dulcolax Pico Liquid contains

- The active substance is sodium picosulfate. Each 5 ml contains 5 mg of sodium picosulfate (present as sodium picosulfate monohydrate) as the active ingredient
- The other ingredients are: carmellose sodium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), glycerol, tutti frutti flavour, saccharin sodium, ethanol, sodium hydroxide (for pH adjustment) and water

What Dulcolax Pico Liquid looks like and contents of the pack

Dulcolax Pico Liquid is a clear, colourless to yellowish or slightly yellowish-brown viscous fruit flavoured solution. It is available in packs of 100 ml and 300 ml.

Marketing Authorisation Holder

Ireland

Opella Healthcare France SAS
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Malta

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Manufacturer

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