

Dulcolax[®] Twelve Plus Pico Liquid



5 mg/5 ml oral solution
sodium picosulfate



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

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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 5 days treatment

What is in this leaflet

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

Dulcolax Twelve Plus Pico Liquid is used for the relief of short-term occasional constipation. Dulcolax Twelve Plus Pico Liquid contains sodium picosulfate and belongs to a group of medicines known as stimulant laxatives, which increase bowel movements. This medicine does not help with weight loss.

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
- Not drinking enough fluid
- 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.

It is recommended to use changes in diet and bulk forming medicines to control constipation before using this medicine.

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 Twelve Plus Pico Liquid

Do not take Dulcolax Twelve Plus Pico Liquid if:

- You are allergic (hypersensitive) to sodium picosulfate or any of the other ingredients in the product (listed in Section 6: Contents of the pack and other information)
- 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)

Do not take Dulcolax Twelve Plus Pico Liquid if any of the above applies to you. Do not use in children under the age of 12 years. If you are not sure, talk to your pharmacist or doctor before taking this medicine.

Does this help with weight loss?

Stimulant laxatives (including Dulcolax Twelve Plus Pico Liquid) do not help with weight loss. They do not reduce the absorption of calories or nutrients. They can cause watery stools (diarrhoea), abdominal cramps and dehydration. Dehydration can seem like weight loss.

Overuse of laxatives may damage your 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 heart. Upsetting this delicate balance can cause incorrect functioning of these vital organs.
- 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.

Other medicines and Dulcolax Twelve Plus Pico Liquid

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Dulcolax Twelve Plus Pico Liquid can affect the way some other medicines work. Also, some other medicines can affect the way Dulcolax Twelve Plus Pico Liquid works.

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

- Water tablets (diuretics) such as bendrofluazide 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 Twelve Plus Pico Liquid.

Pregnancy and breast-feeding

Talk to your pharmacist or doctor before taking Dulcolax Twelve Plus Pico Liquid if you are pregnant, planning to become pregnant or are breast-feeding.

Important information about some of the ingredients in Dulcolax Twelve Plus Pico Liquid

Dulcolax Twelve Plus Pico Liquid contains 4.8 vol % ethanol (alcohol), i.e. up to 480 mg per 10 ml dose, equivalent to 10.4 ml beer or 4.3 ml of wine per 10 ml dose. This may be harmful for people with a drink problem (alcoholism). This should also be taken into account in pregnant or breast-feeding women, children and high risk groups such as those with liver disease or epilepsy.

Dulcolax Twelve Plus Pico Liquid contains the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate. These ingredients may cause allergic reactions, which may not happen after the first dose. The signs may include: a rash, swelling of your skin, mouth and face which may cause swallowing or breathing problems.

3. How to take Dulcolax Twelve Plus Pico Liquid

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

Adults and children over 12 years: one to two 5 ml spoonfuls at night.

This should not be used in children and adolescents under the age of 12 years.

If you have not taken Dulcolax Twelve Plus Pico Liquid before, start with one 5 ml spoonful and increase to two if necessary. When your bowel regularity has returned to normal, the dose can usually be stopped.

Length of treatment

This product should **not be used every day for more than 5 days**. If you need laxatives every day, then you should see your doctor to find the cause of your constipation. **Overuse can be harmful.**

If you take more Dulcolax Twelve Plus Pico Liquid than you should

It may be harmful to:

- Take too much Dulcolax Twelve Plus Pico Liquid
- Take Dulcolax Twelve Plus Pico Liquid for too long

This is because taking too much for too long may lead to:

- Imbalance of fluid and salts in the body. This can affect the tightness of muscles such as those in the bowel. It can also affect the salts in the blood.
- Low levels of potassium in the blood (called 'hypokalaemia'). This can make you tired, dizzy, make your muscles weak and cause an uneven heartbeat.
- Dehydration, making you thirsty, feel faint and giving you headaches. It can also mean you cannot pass enough urine.

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 Twelve Plus Pico Liquid can cause side effects, although not everybody gets them. If you experience any of the following side effects, please stop taking the medicines and see your doctor straight away:

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dulcolax Twelve Plus Pico Liquid

- Keep this medicine out of the sight and reach of children
- Do not take Dulcolax Twelve Plus 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 protect the environment

6. Contents of the pack and other information

What Dulcolax Twelve Plus Pico Liquid contains

- 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 Twelve Plus Pico Liquid looks like and contents of the pack

Dulcolax Twelve Plus Pico Liquid is a clear, colourless to yellowish or slightly yellowish-brown viscous fruit flavoured solution. It is available in packs of 90 ml, 100 ml, 250 ml and 300 ml.

Not all pack sizes are marketed.

The Marketing Authorisation is held by:

Sanofi,
410 Thames Valley Park Drive,
Reading, Berkshire,
RG6 1PT, UK.
Tel: 0845 372 7101
Email: uk-medicalinformation@sanofi.com

Dulcolax Twelve Plus Pico Liquid is manufactured at:

Istituto De Angeli S.r.l.
Località Prulli n. 103/c
50066 Reggello (FI), Italy

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