

Package Leaflet: Information for the user

Dulcolax[®]

Pico Perles

[picture of 4 x capsules]

2.5 mg capsules
sodium picosulfate

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. You need to take DULCOLAX PICO PERLES as instructed in this leaflet to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact your pharmacist or doctor if your symptoms worsen or do not improve after five days treatment
- If a side effect occurs and gets troublesome, or seems serious to you, or if you experience any side effect not listed in this leaflet, please tell your pharmacist or doctor

In this leaflet:

1. What DULCOLAX PICO PERLES are and what they are used for
2. Before you take DULCOLAX PICO PERLES
3. How to take DULCOLAX PICO PERLES
4. Possible side effects
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6. Further information

1. WHAT DULCOLAX PICO PERLES ARE AND WHAT THEY ARE USED FOR

- DULCOLAX PICO PERLES contain a medicine called sodium picosulfate. This belongs to a group of medicines called laxatives
- DULCOLAX PICO PERLES are used for relief of constipation
- DULCOLAX PICO PERLES gently stimulate 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. BEFORE YOU TAKE DULCOLAX PICO PERLES

Do not take DULCOLAX PICO PERLES if:

- You are allergic (hypersensitive) to sodium picosulfate or any of the other ingredients in the product (listed in Section 6: Further 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 or large intestine)

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking this medicine.

Taking other medicines

Please tell your pharmacist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because DULCOLAX PICO PERLES can affect the way some other medicines work. Also, some other medicines can affect the way DULCOLAX PICO PERLES 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

Before taking DULCOLAX PICO PERLES tell your pharmacist or doctor if you are not sure if any of the above applies to you.

Pregnancy and breast-feeding

Talk to your pharmacist or doctor before taking DULCOLAX PICO PERLES if you are pregnant, planning to become pregnant or are breast-feeding.

3. HOW TO TAKE DULCOLAX PICO PERLES

If this medicine is from your doctor or pharmacist, do exactly as they have told you. Otherwise, follow the instructions below. If you do not understand the instructions, or if you are not sure, ask your pharmacist or doctor.

As with all laxatives, DULCOLAX PICO PERLES should not be taken every day for more than five days. If you need laxatives every day, or if you have abdominal pain which does not go away, you should see your doctor.

How much to take

Adults and children over 10 years

- Take two to four capsules (5 mg to 10 mg) 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 PERLES should only be given to children between the ages of 4 and 10 if recommended by a doctor. The usual dose for children is:

- Give one to two capsules (2.5 mg to 5 mg) at night

Children under 4 years

DULCOLAX PICO PERLES is not recommended for children under 4 years.

If you take more DULCOLAX PICO PERLES 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 PERLES 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 (affect 1 in 10 people or more)

- Diarrhoea

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

- Abdominal discomfort, cramps or pain

Uncommon side effects (affect 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 via the national reporting system (see details below):

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DULCOLAX PICO PERLES

- Keep this medicine out of the sight and reach of children
- Do not take DULCOLAX PICO PERLES after the expiry date which is stated on the carton or bottle label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C
- Keep the bottle within the outer carton in order to protect from light
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. FURTHER INFORMATION**What DULCOLAX PICO PERLES contain**

- Each capsule contains 2.5 mg of sodium picosulfate (present as monohydrate) as the active ingredient
- The other ingredients are: propylene glycol, macrogol 400, gelatin, glycerol and purified water

What DULCOLAX PICO PERLES look like and contents of the pack

DULCOLAX PICO PERLES are small, pearl-shaped soft gelatin capsules. They are available in packs of 20 and 50 capsules.

The Marketing Authorisation is held by:

sanofi-aventis Ireland Ltd.

T/A SANOFI

Citywest Business Campus

Dublin 24

Ireland

Batch release is carried out by:

CHINOIN Pharmaceutical and Chemical Works Private Co. Ltd
(CHINOIN Private Co. Ltd.)

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Hungary

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