



# Dulcolax<sup>®</sup>

## Pico Liquid



5mg / 5ml oral solution  
sodium picosulfate

### Package leaflet: Information for the user

#### 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 Liquid 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 Liquid is and what it is used for
2. 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. Further 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.
- 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. 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 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 and large intestine)

Do not take DULCOLAX PICO Liquid 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 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 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 PICO Liquid.

##### Pregnancy and breast-feeding

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

### Important information about some of the ingredients in DULCOLAX PICO Liquid

DULCOLAX PICO Liquid contains 5.9% ethanol (alcohol), which is up to 480 mg per dose. This is equivalent to 12 ml beer or 5 ml wine per 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 PICO Liquid contains the preservatives methyl parahydroxybenzoate, propyl parahydroxybenzoate and the colouring agent sunset yellow (E110). 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 PICO LIQUID

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 you are not sure, ask your pharmacist or doctor.

**As with all laxatives, DULCOLAX PICO Liquid should not be taken every day for long periods. 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

- 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.

#### United Kingdom

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

#### Ireland

HPRA Pharmacovigilance,

Earlsfort Terrace,

IRL – Dublin 2.

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

#### Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gżira

Website: [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)

e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

### 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
- 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 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, aroma tutti frutti (flavouring), saccharin sodium, colouring sunset yellow (E110), 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, yellowish-orange, slightly viscous fruit flavoured solution. It is available in packs of 30 ml, 100 ml and 300 ml.

#### The Marketing Authorisation is held by:

Boehringer Ingelheim Limited, Ellesfield Avenue, Bracknell, Berkshire, RG12 8YS, United Kingdom.

#### DULCOLAX PICO Liquid is manufactured at:

Istituto De Angeli S.r.l.

Località Prulli n. 103/c

50066 Reggello (FI), Italy

This leaflet was revised in September 2014.

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