Code 159

Package leaflet: Information for the patient

Sodium Picosulfate 5mg/5ml Oral Solution

Sodium Picosulfate

This medicine will be called Sodium Picosulfate Solution in this leaflet.

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. You need to take Sodium Picosulfate 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 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).

What is in this leaflet:

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

1. What Sodium Picosulfate Solution is and what it is used for

This medicine contains sodium picosulfate as the active ingredient. Sodium picosulfate belongs to a group of medicines known as stimulant laxatives, which increase bowel movements. It has a dual action, stimulating the muscles of both the large intestine and rectum to bring relief from constipation. It may restore the sensation or desire for bowel movements so helping your body to regain its natural rhythm.

Sodium Picosulfate Solution is used for the short term occasional relief of constipation. 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 fluids
- Loss of "tone" of the bowel muscle 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 can cause 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 Sodium Picosulfate Solution

Do not take Sodium Picosulfate Solution if:
- You know you are allergic to sodium picosulfate or any of the other ingredients of this medicine (listed in section 6)
- You suffer from any of the following intestinal problems: ileus, intestinal obstruction, acute surgical abdominal conditions like acute appendicitis or acute inflammatory bowel disease
- You are suffering from severe dehydration
- You have severe abdominal pain with nausea and vomiting.

Warnings and precautions
Do not take Sodium Picosulfate Solution 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 sodium picosulfate) 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 Sodium Picosulfate Solution
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including any that you may have bought without a prescription including herbal medicines. In particular:
- Diuretics (water tablets to increase urine production)
- Adrenocorticosteroids (steroid medicines such as prednisolone)
- Antibiotics to treat infections.

Pregnancy, breast-feeding and fertility
Talk to your pharmacist or doctor before taking this medicine, if you are pregnant, think you may be pregnant or are planning to have a baby, or you are breast-feeding.

Continued, please turn over.

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Driving and using machines
You may feel dizzy or faint while taking this medicine. Do not drive or operate machinery if you are affected.

Sodium Picosulfate Solution contains liquid maltitol (E965), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), sunset yellow (E110), and propylene glycol (E1520)
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains liquid maltitol (E965).
- This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).
- This medicine contains sunset yellow (E110) which may cause allergic reactions.
- This medicine contains less than 1mmol sodium (23mg) per 5ml, that is to say essentially “sodium free”.
- This medicine contains 4.8mg propylene glycol in each 5ml which is equivalent to 9.6mg/10ml.

3. How to take Sodium Picosulfate Solution

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.

Dose for constipation
Adults and children over 12 years of age: One to two 5 ml spoonfuls to be taken each day.
This medicine should not be used in children or adolescents under the age of 12 years.

If you have not taken sodium picosulfate before, start with one 5 ml spoonful and increase to two if necessary. When your bowel regularity has returned to normal, the dose should be reduced and 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 out the cause of your constipation. **Overuse can be harmful.**

If you take more Sodium Picosulfate Solution than you should
It may be harmful to take Sodium Picosulfate Solution for too long. This is because 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 hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

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

If you forget to take Sodium Picosulfate Solution
If you miss a dose don’t worry, just miss this dose then carry on with normal routine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor straight away if you notice any of the following:
- Skin rash, swelling of the face or throat, as these may be the symptoms of a serious allergic reaction.

The following other side-effects have been reported:

Very common (may affect more than 1 in 10 people):
- Diarrhoea.

Common (may affect up to 1 in 10 people):
- Stomach discomfort, cramps or pain.

Uncommon (may affect up to 1 in 100 people):
- Dizziness
- Feeling or being sick.

Not known (frequency cannot be estimated from the available data):
- Fainting.
- 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.

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 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 Sodium Picosulfate Solution

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C. Keep the bottle in the outer carton.
Discard 28 days after opening.
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 Sodium Picosulfate Solution contains
Each 5 ml of solution contains 5 mg of the active ingredient, sodium picosulfate (as monohydrate).
The other ingredients are xanthan gum, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), liquid maltitol (E965), sodium saccharin, strawberry flavour (containing propylene glycol (E1520), ethanol and flavouring substances), sunset yellow (E110), citric acid anhydrous, sodium citrate dihydrate and purified water. (See also end of section 2 “Sodium Picosulfate Solution contains”).

What Sodium Picosulfate Solution looks like and contents of the pack
The medicine is a clear, orange coloured liquid, with a fruit-like odour and taste.
It is supplied to your pharmacist in bottles containing 100 ml or 300 ml. Both pack sizes may not be available.

Marketing Authorisation Holder:
Kent Pharma UK Limited, 2nd Floor, Connect 38,
1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufacturer: L-A-W Services GmbH, Leipziger Arzneimittelwerk, Elisabeth-Schumacher-Str. 54-56, 04328 Leipzig, Germany.

This leaflet was last revised in June 2024.

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