

CASEN PHOSPHO-SODA 24.4 g / 10.8 g oral solution

Disodium phosphate dodecahydrate - Sodium dihydrogen phosphate dihydrate

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What Phospho-soda is used for

Phospho-Soda is a laxative. It is used in case of severe constipation. You must also adapt your eating habits if you suffer from constipation.

Phospho-Soda is used to prepare the bowel for a surgical procedure or a bowel examination.

You must talk to a doctor if you do not feel better or if you feel worse.

How Phospho-soda works

It works by osmotic processes to increase fluid retention in small bowel lumen.

Before you use Phospho-soda

- When you must not use it

- Do not use this product if you are allergic to the active substance or any of the other ingredients of this medicine
- If you suffer from nausea or stomach ache; in this case there is actually a risk of kidney failure;
- If you are younger than 18 years, you cannot use Phospho-Soda as bowel cleansing (but you can use it as laxative).
- In case of:
 - kidney disease;
 - overactivity of the parotid glands (primary hyperparathyroidism) associated with high concentrations of calcium in blood.

- symptomatic heart disease;
- ascites (fluid accumulation in the abdominal cavity);
- known or suspected occlusion in the stomach or the bowel;
- colon hypertrophy (megacolon);
- perforation in the gastrointestinal tract;
- bowel occlusion (ileus);
- progressing inflammatory bowel disease (such as Crohn's disease or bleeding rectal colitis).
- Phospho-Soda cannot be used in combination with other laxatives containing sodium phosphate.

- Before you start to use it

Talk to your doctor or pharmacist before using Phospho-Soda

- If you are already taking other medicines, also see Section «Taking other medicines».
- In elderly or frail people, the fluid and electrolyte (water-salt) balance may be impaired with the use of Phospho-Soda. This disturbance may be fatal. Talk to your doctor before using Phospho-Soda.
- During the use of Phospho-Soda, faeces will be abundant and more liquid. Also it is very important that you drink as much water as possible. In fact, if you drink too little, there is a risk of dehydration and too weak volemia (circulating blood volume).
- If you suffer from any of the following:
 - heart disease, such as myocardial infarction or angina pectoris (angina);
 - hypotension;
 - dehydration;
 - slowing down of gastric or intestinal activity;
 - colon inflammation;
 - fluid and electrolyte imbalance
- If you do not absorb sufficient liquid.
- If you are on a sodium-free (salt-free) diet.
- After a gastrointestinal procedure, because gastrointestinal transit may be delayed.
- If you have an artificial anus.
- In case of use of diuretics, of some antihypertensives and anti-

inflammatory analgesics (of NSAID type), kidney failure may occur.

- This medicine takes usually about half an hour to 6 hours to act following administration. If no intestinal transit is seen within 6 hours following the use of the first or the second dose of Phospho-Soda, discontinue immediately the administration and talk to a doctor.
- Dependency and intestinal problems may occur if you use Phospho-Soda frequently or on the long term.
- You can talk to your doctor if one of the warnings mentioned concerns you or have affected you in the past. Talk to your doctor before using Phospho-Soda.

Pregnancy and lactation

Do not take Phospho-soda if you are pregnant, trying to get pregnant or think you may be pregnant.

Phospho-Soda cannot be used during pregnancy, unless its use is completely necessary and it is administered under medical monitoring.

Do not take Phospho-soda if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

It is not known whether Phospho-Soda enters nursing milk. Since then, if you want to use Phospho-Soda, collect your milk and dispose of it. Follow these steps from the last dose to 24 hours following the second dose (see «Use in case of bowel cleansing»). Do not breast-feed within 24 hours following the second dose of Phospho-Soda.

There are no data on the effect of Phospho-Soda on male and female fertility.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Ask your doctor if you are taking the following medicines:

- medicines against hypertension (e.g calcium channel blockers, angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBS));
- medicines against heart diseases,
- diuretics (tablets for increasing urine),
- parathormone (medicine for osteoporosis),
- lithium or other products susceptible of affecting electrolyte balance,
- medicines that modify heart rhythm.

The use of Phospho-Soda may delay or hinder completely intestinal absorption of medicines. This applies in particular to the following substances:

- contraceptives taken by oral route (by the mouth),
- medicines against epilepsy,
- medicines used for diabetes
- antibiotics.

The concomitant use of other preparations based on sodium phosphate is not permitted.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Phospho-Soda with food and drink

This medicine contains 5.0 g of sodium per 45 mL bottle. Take into account that patients must control their sodium diet supply.

Phospho-Soda contains sodium

Each bottle contains 5.0 g of sodium per 45 mL. If you are on a sodium-free (salt-free) diet, you cannot use this medicine.

How to use Phospho-Soda

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Phospho-Soda for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you must use Phospho-Soda as preparation for a bowel examination, tell your doctor so that new measures can be taken for the examination. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

High doses of Phospho-Soda are dangerous for children and patients with constipation. These can cause excess phosphate and sodium in blood and deficit of calcium and potassium in blood. These disorders can cause body acidification, which can sometimes be fatal.

In case of overdosage or accidental intake, the following symptoms can occur: dehydration, hypotension, tachycardia, slowing down of pulse, cardiac arrest, shock, acceleration of breathing, respiratory problems, gasping, seizures, large bowel paralysis, anxiety, pain in the lower abdomen.

Cases of complete recovery after overdosage have been reported, both in children receiving accidentally Phospho-Soda and patients with constipation.

In case of overdosage, it is essential to restore water balance.

Intravenous administration of 10% calcium gluconate may be sometimes necessary.

Hospitalisation is recommended.

ATTENTION:

- Drink enough water or clear liquids to prevent complete dehydration or too low volemia (volume of blood circulating in the body).

- «Clear liquid» means water, clear soup (not thick), fruit juice without pulp, tea or black coffee, clear beverages not containing carbonic gas.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Phospho-Soda.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Phospho-soda* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Phospho-Soda can cause dizziness, probably as a result of dehydration. It can cause a mild to moderate effect on the ability to drive cars or use machines.

Side effects

Like all medicines, Phospho-Soda can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Side effects that might occur include: dizziness, headache, nausea, abdominal pain, abdominal distension, diarrhea, vomiting, tremor, body weakness, chest pain and allergic reaction.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Phospho-soda

- Storage

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

Store below 30°C.

- Disposal

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.

Product Description

- What it looks like

45 mL polyethylene bottles, colourless solution of ginger-lemon flavour, with no precipitation or turbidity.

- Ingredients

- Active ingredients: Disodium phosphate dodecahydrate and Sodium dihydrogenphosphate dihydrate

- Inactive ingredients: glycerine, sodium saccharin, ginger-lemon flavour (ginger oil, alcohol, lemon oil, citric acid, water), sodium benzoate and purified water.

- MAL number:
MAL18081001X

Manufacturer

CASEN RECORDATI, S.L.
Autovía de Logroño, km 13,300
50180 UTEBO (Zaragoza) SPAIN

Product Registration Holder

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Date of revision

-10/03/2022

Serial Number

NPRA (R2/1) 220510/880