

Package leaflet: Information for the user

Phospho-soda 24.4 g / 10.8 g oral solution

Sodium Dihydrogen Phosphate Dihydrate / Disodium Phosphate Dodecahydrate

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, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Phospho-Soda is and what it is used for

Phospho-soda is a bowel cleanser that acts by increasing the water content of your stools. It is a solution which you take by mouth and it comes in packs containing two 45 ml bottles. Each bottle contains one dose which must be diluted with water before use (see Section 3).

You need to take Phospho-soda in order to clean your bowel (also called large intestine or colon) before your endoscopy, bowel surgery or X-ray examination. It is important that your bowel is completely empty so that the doctors can see it clearly.

Phospho-soda is not a treatment for constipation.

Phospho-soda is indicated in adults.

2. What you need to know before you take Phospho-Soda

Do not take Phospho-soda if you:

- are allergic to disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate or any of the other ingredients of this medicine (listed in section 6);
- are under the age of 18 years;
- feel sick or are vomiting, or are suffering from abdominal pains;
- have kidney disease;
- suffer from symptomatic heart disease;
- have an abnormal build up of fluid in the space between the lining of the abdomen and the abdominal organs;
- know or suspect you have an obstruction, perforation or paralysis of your bowels;
- have inherited or acquired enlargement of the large intestine (megacolon);

- suffer from active inflammatory bowel disease;
- have overactive parathyroid glands (hyperparathyroidism) ;

Do not take Phospho-soda in combination with any other laxative products containing sodium phosphate.

Check with your doctor if you think any of the above could apply to you. Your doctor will then decide if Phospho-soda is suitable for you.

Warnings and precautions

Talk to your doctor , pharmacist or nurse before taking Phospho-soda

Take special care with Phospho-soda if you:

- are frail or elderly (65 years old or more);
- have a heart or kidney condition;
- suffer from changes to levels of salts in your body (electrolyte imbalances) or are at risk of such changes, for example if you are dehydrated.
- have low blood pressure or reduced movement in part or all of your intestines;
- have had a colostomy or an ileostomy;
- have had any other kind of operation or surgery on your stomach or intestines;
- are on a low-sodium (low-salt) diet (*See also important information about some of the ingredients of Phospho-soda at the end of section 2*).

Please consult your doctor, if you think any of the statements above are applicable to you now or at any time in the past. Phospho-soda could slightly alter the rhythm of the heart as a result of electrolyte imbalances, so you may need closer medical supervision during your treatment.

After taking Phospho-soda you should expect to produce frequent, liquid stools. You should drink as much clear liquid (see Section 3) as possible so that you do not become dehydrated.

This product usually works within 30 minutes to 6 hours. If you have no bowel movement within 6 hours of taking either the first or the second dose, contact a doctor immediately because you could become dehydrated.

Other medicines and Phospho-soda

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- medicines for the treatment of high blood pressure (hypertension) or angina (e.g calcium channel blockers, angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs));
- medicines for emptying the bladder (diuretics);
- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin;
- certain medicines for mental disorders (containing lithium);
- any other medicines that could make you dehydrated or change various salt levels (potassium, sodium, phosphate or water) in your body (your electrolyte balance);
- medicines that alter the rhythm of your heart;
- parathyroid hormone medicines;
- medicines regularly taken by mouth: for example, oral contraceptives, and medicines for epilepsy or diabetes or antibiotics, because Phospho-soda may delay or completely prevent the absorption of these oral medicines, making them less effective or ineffective.

Check with your doctor or pharmacist, if you are unsure.

Phospho-soda with food and drink

Please see Section 3 of this leaflet.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not use this medicine during pregnancy unless your doctor considers it necessary. If you are breast-feeding, it is advised that breast milk is expressed and discarded from the first dose to 24 hours after the second dose of the bowel cleansing solution. You should not breast-feed your child for 24 hours after taking the second dose of Phospho-soda.

Frail people and the elderly (65 years of age and over):

Please pay special attention to the advice given in the sub-sections Take special care with Phospho-soda and Taking other medicines (above) as well as to the instructions on How to take this medicine in Section 3 (below). It may be that you will need special medical supervision.

Driving and using machines

Do not drive, use machinery or tools if you feel tired or dizzy, or think you may be dehydrated, after taking Phospho-soda. You should also stay within easy reach of toilet facilities after taking this medicine.

Phospho-soda contains sodium

This medicine contains 5000 mg sodium (main component of cooking/table salt) in each 45 ml dose. This is equivalent to 250% of recommended maximum daily dietary intake of sodium for an adult. Consideration should therefore be given to the potential harm to patients requiring a low-sodium (low-salt) diet.

Phospho-soda contains ethanol

This medicine contains 29 mg of alcohol (ethanol) in each 45 ml dose. The amount in 45 ml of this medicine is equivalent to less than 0.73 ml beer or 0.29 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Phosphosoda contains sodium benzoate

This medicine contains 15 mg Sodium benzoate (E 211) in each 45 ml dose.

3. How to take Phospho-Soda

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

- Before you first start taking Phospho-soda up until after your examination, it is important that you drink only “clear liquid.” Do not eat any solid food.
- “Clear liquid” means water; clear soup, or soup that has been strained to remove any solids; fruit juices without pulp (but not red or purple juices); black tea or black coffee and clear fizzy/non fizzy drinks e.g. lemonade.
- To help prevent you feeling sick while taking this medicine, you should drink as much clear liquid as you can.
- Phospho-soda may cause a number of diarrhoea-like bowel movements. It often starts to work within 30 minutes and may go on working for up to 6 hours. Please stay within easy reach of a toilet until your bowel movements have stopped.

If you have had no bowel movement within 6 hours of taking either the first dose or the second dose, you must contact a doctor immediately, because you could become dehydrated. You must start taking Phospho-soda the day before your hospital appointment.

How to take your first or second dose

To do this, dilute the contents of **one** bottle (45 ml) of Phospho-soda in half a glass (120 ml) of cold water. Drink this and follow it with at least one full glass (240 ml) of cold water. Drink as much clear liquid as possible to replace the fluids lost during bowel movements.

When to take your first or second dose

Please refer to the two boxes below, depending on the time of your hospital appointment.

If you do not follow these instructions completely, it may not be possible to proceed with your examination or surgery.

MORNING APPOINTMENTS 8.00 A.M. – 12 NOON

THE DAY BEFORE YOUR APPOINTMENT

At **7a.m.** drink at least one full glass (240 ml) of clear liquid for breakfast. You may drink more if you wish.

Straight afterwards take your **first dose**. (See above).

At **1p.m.** drink at least three more full glasses (720 ml) of clear liquid for lunch. During the afternoon, you may continue to drink clear liquid to satisfy your thirst.

At **7p.m.** drink at least one full glass (240 ml) of clear liquid for supper. You may drink more if you wish.

Straight afterwards take your **second dose**. (See above).

You may continue to drink clear liquid up until midnight to satisfy your thirst. Clear liquid taken after midnight may cause further visits to the toilet resulting in sleep loss.

AFTERNOON APPOINTMENTS 12 NOON – 5.00P.M.

THE DAY BEFORE YOUR APPOINTMENT

At **1p.m.** eat a light snack, e.g. soup and a sandwich for lunch.

Do not eat any more solid food until after your hospital appointment. During the afternoon, you may drink clear liquid to satisfy your thirst.

At **7p.m.** drink at least one full glass (240 ml) of clear liquid for supper. You may drink more if you wish.

Straight afterwards take your **first dose**. (See above).

During the evening, make sure you drink at least three more full glasses (720 ml) of water or clear liquid before going to bed.

THE DAY OF YOUR APPOINTMENT

At **7a.m.** drink at least one full glass of clear liquid for breakfast. You may drink more if you wish.

Straight afterwards take your **second dose**. (See above).

You may continue to drink clear liquid up until 8a.m. to satisfy your thirst. Clear liquid taken after 8a.m. may cause further visits to the toilet resulting in difficulties in getting to your hospital appointment.

After your hospital appointment, make sure you drink plenty of fluid to replace fluid lost when you were taking Phospho-soda.

If you take more Phospho-soda than you should

If you may have taken more Phospho-soda than you should, talk to a doctor or pharmacist immediately, because you may be dehydrated, have problems with your heart and circulation, have breathing difficulties, feel anxious or have colic pain.

If you forget to take Phospho-soda

Please consult your doctor for advice. Do not take a double dose to make up for a forgotten dose..

4. Possible side effects

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

Very rarely, Phospho-soda can cause serious allergic reactions with or without a rash. Tell your doctor **immediately** or contact the emergency department of your nearest hospital if your hands, face, lips, throat or tongue start to swell, or if you have difficulty in breathing or swallowing.

Other possible side effects with Phospho-soda:

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

feeling sick, abdominal pain, bloating and diarrhoea, chills, weakness and dizziness.

Common (may affect up to 1 in 10 people):

Vomiting, chest pain and headache.

Uncommon (may affect up to 1 in 100 people):

Dehydration

Rare (may affect up to 1 in 1,000 people):

A build up of calcium in the kidneys

Very rare (may affect up to 1 in 10,000 people):

Heart attack, palpitations, low blood pressure, changes in the amounts of salts (electrolytes) in the blood (which may lead to twitches and spasms), muscle cramps, pins and needles, loss of consciousness, and kidney failure.

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

Hyponatraemia (low sodium concentration in the blood which may lead neurological disorders, such as confusion, coma or convulsions)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Phospho-Soda

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 pack after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Once opened, use immediately. Discard any unused solution.

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 Phospho-soda contains

- The active substances are Sodium Dihydrogen Phosphate Dihydrate 24.4 g and Disodium Phosphate

Dodecahydrate 10.8 g in each 45 ml dose.

- The other ingredients are: Sodium Benzoate (E211); Sodium Saccharin; Glycerol; Purified Water and Ginger Lemon flavour comprising of Oleoresin Ginger; Alcohol; Oil Lemon; Partially Deterpined Oil Lemon; Citric Acid and Purified Water.

What Phospho-soda looks like and contents of the pack

Phospho-soda is a clear colourless oral solution with a ginger-lemon odour, which comes in packs containing 2 or 100 45 ml bottles with screw caps. Each bottle contains one dose. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Casen Recordati, S.L., Autovia de Logroño, km 13,300, 50180 Utebo, Zaragoza, Spain.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: Recordati Ireland Ltd. Tel: + 353 21 4379421

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Denmark: Phosphoral oral opløsning

Finland: Phosphoral oraaliliuos

France: Recholan, solution buvable

Germany: Phospho-soda Lösung zum Einnehmen

Greece: Phospho-soda

Ireland: Phospho-soda oral solution

Netherlands: Phosphoral, drank

Portugal: Phospho-Soda Solução oral

Spain: Fosfosoda solución oral

Sweden: Phosphoral oral lösning

United Kingdom (Northern Ireland): Phospho-soda oral solution

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Other sources of information

Detailed information on this medicine is available on the website of HPRA, www.hpra.ie.