

PHOSPHO[®]-SODA

Oral Solution

monobasic sodium phosphate dihydrate and dibasic sodium phosphate dodecahydrate

Consumer Medicine Information

WARNING: Life threatening dehydration and/or electrolyte disturbances may occur in some people. Read the section with the heading 'Before you take PHOSPHO-SODA' (below) and, if you think you *could* be at risk, discuss with your doctor and do not take this product without his/her approval.

What is in this leaflet

This leaflet answers some common questions about PHOSPHO-SODA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PHOSPHO-SODA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Read this leaflet carefully before you take this medicine.

If you are having an operation or x-ray of the bowel or colonoscopy, read all of these instructions at least two days before your examination.

Keep this leaflet with the medicine.

You may need to read it again.

What PHOSPHO-SODA is used for

This medicine is used as part of a bowel cleansing procedure before

x-ray of the bowel, colonoscopy (looking into the bowel with an instrument) or before a bowel operation.

PHOSPHO-SODA is for use in adults.

It works by producing bowel motions which cleanse the bowel. It usually works within 30 minutes, although it may take as long as 6 hours. Expect frequent liquid stools.

Stop using this product and consult a doctor if you do not have a bowel movement within 6 hours.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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. Children should be careful when riding bicycles or climbing trees.

Before you take PHOSPHO-SODA

When you must not take it

Do not take PHOSPHO-SODA if you:

- have an allergy to any of the ingredients listed at the end of this leaflet
- are under 18 years of age

- have hard, solidified bowel motions (faecal impaction)
- have non-functioning small bowel (paralytic ileus)
- know or suspect you have an obstruction, perforation or paralysis of your bowels
- have low movement of the intestines (hypomotility)
- have large bowel which was present from birth (Hirschsprung's disease/congenital megacolon)
- have acquired enlargement of the large intestine (megacolon);
- have the natural opening of the anus closed (imperforate anus)
- have an abnormal buildup of fluid in the space between the lining of the abdomen and the abdominal organs, including around the stomach (ascitic conditions)
- have overactive parathyroid glands (hyperparathyroidism)
- have an active inflammatory bowel disease
- have serious kidney problems (kidney disease)
- have symptomatic heart disease
- have an altered sense of smell or taste
- do not tend to drink much liquid
- feel sick (nausea)
- are vomiting
- have abdominal (stomach) pain.

Do not take PHOSPHO-SODA in combination with any other

laxative products containing sodium phosphate.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

It is very important that you drink extra clear liquids, before, and after taking this medicine.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- are in poor general health
- are frail or elderly (65 years old or more). It may be that you will need special medical supervision
- 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 as this medicine contains 5000 mg sodium (main component of cooking/table salt) in each 45mL dose. This is equivalent to 250% of recommended maximum daily dietary intake of sodium for an adult. (See also section “Product Description”)
- you are pregnant or plan to become pregnant or are breast-feeding.

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.

Your doctor can discuss with you the risks and benefits involved.

Please consult your doctor before you start taking PHOSPHO-SODA. 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.

If you are elderly, tell the doctor your age. He or she may need to check if it is safe for you to take PHOSPHO-SODA. It is very important that you drink more liquids, before, and after taking PHOSPHO-SODA.

After taking PHOSPHO-SODA you should expect to produce frequent, liquid stools. You should drink as much clear liquid (see “Clear Liquids List” in “How & when to take it”) 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.

Taking other medicines

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

Some medicines and PHOSPHO-SODA may interfere with each other.

These include:

- medicines which increase the volume of urine (diuretics)
- medicines used to treat some types of mental disorders, depressions or mood swings (lithium preparations)
- any medicine that could make you dehydrated or change various salt levels (potassium, sodium, phosphate or water) in your body (your electrolyte balance)
- medicines used to treat high blood pressure, angina and some other heart conditions (e.g. angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers and calcium channel blockers)
- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- Non-steroidal anti-inflammatory drugs (NSAIDs) – such as aspirin- that might cause fainting or irregular heartbeat (i.e. that can prolong the QT interval). There are many medicines that can have this effect, so please ask your doctor or pharmacist if any that you are taking might have this effect
- 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.

These medicines may be affected by PHOSPHO-SODA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Ask your doctor or pharmacist if unsure.

If you are diabetic, the liquid diet recommended with this medication may affect your glucose blood levels and adjustment of your insulin or oral anti-diabetic medicine may be necessary.

How to take PHOSPHO-SODA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

Do not give this medicine to children under 18 years of age.

How much to take

Adults: The recommended dosage is 45 mL (one full bottle) as a 1st dose to be followed 10 to 12 hours later by a 2nd dose (another full bottle).

Depending on whether the medical procedure is intended to be performed at early morning or later, two alternative dosage regimens are set out below:

How & when to take it

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.

The intake of clear liquids is an essential part of this regimen.

Please refer to clear liquids list below.

PHOSPHO-SODA must be diluted with water before use (see the instructions for dilution below).

First dose (1st bottle):

Take as follows:

- Mix 15 mL (one third of the bottle) of PHOSPHO-SODA into a full glass (approximately 250 mL) of clear liquid (see list below) and drink.

Repeat this process two more times within the next 20 minutes.

Between the first and second doses:

Drink at least three more glasses (approximately 250 mL each) of clear liquids or more if desired to prevent dehydration and to ensure that the bowel remains easily examinable for the procedure.

Second dose (2nd bottle):

Take as follows:

- Mix 15 mL (one third of the bottle) of PHOSPHO-SODA into a full glass (approximately 250 mL) of clear liquid (see list below) and drink.

Repeat this process two more times within the next 20 minutes.

If you are having an early morning x-ray or colonoscopy:

Take the first dose at 7 a.m. on the day before the procedure.

Take the second dose at 7 p.m. on the evening before the procedure.

For early morning procedures, on the day before the procedure, you should only take clear liquids (see below) for breakfast, lunch and dinner and between doses.

No solid food, milk or milk products should be taken on the day before the procedure. You should not drink anything coloured red or purple.

If you are having a mid-morning (or later) x-ray or colonoscopy:

Take the first dose at 7 p.m. on the evening before the procedure.

Take the second dose at 7 a.m. (or at least 3 hours before leaving for the appointment) on the morning of the procedure.

For mid-morning (or later) procedures, on the day before the procedure, you may have a light snack for lunch. After this time you

should only take clear liquids (see below).

No solid food, milk or milk products should be taken after lunch on the day before the procedure. You should not drink anything coloured red or purple.

To help prevent you feeling sick while taking this medicine, you should drink as much clear liquid as you can.

Clear Liquids List:

Beverages:

- Water, tea or coffee (no milk or non-dairy creamer). Sweeteners are acceptable
- Carbonated or non-carbonated soft drinks (not coloured red or purple)
- Fruit flavoured cordials (not coloured red or purple)
- Strained fruit juices without pulp
- Do not drink any alcoholic beverages.

Soups:

- Strained low sodium chicken or beef soup without solid material.

Do not drink anything coloured red or purple.

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.

After the procedure: you should drink plenty of fluid to replace fluid lost during the preparation for the procedure.

If you are having an operation on the bowel, you will be given your doses of PHOSPHO-SODA in the hospital under medical and nursing supervision.

In some cases, your doctor may decide to modify the above dosage instructions. If this occurs and you have any questions, ask your doctor.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PHOSPHO-SODA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using PHOSPHO-SODA

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not take PHOSPHO-SODA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PHOSPHO-SODA.

This medicine helps most people as part of a bowel cleansing procedure before x-ray of the bowel, colonoscopy or before a bowel operation, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

PHOSPHO-SODA may cause a temporary decrease in the volume of the blood and changes in the amounts of salts in the blood, which, in healthy and fit people, return to normal in 24 hours.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- if your hands, face, lips, throat or tongue start to swell or if you have difficulty in breathing or swallowing.

Very rarely (affects less than 1 user in 10,000) PHOSPHO-SODA can cause serious allergic reactions with or without a rash.

Tell your doctor as soon as possible if you notice any of the following:

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 buildup 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).

There have been occasional reports of :

- sleep loss
- hunger
- feeling thirsty
- rash
- anal irritation.

After using PHOSPHO-SODA

Storage

Keep PHOSPHO-SODA in a cool dry place where the temperature stays below 30°C.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

PHOSPHO-SODA is a clear, colourless, ginger-lemon odour, aqueous liquid.

Ingredients

Each 45 mL of PHOSPHO-SODA contains:

Active ingredients

Monobasic sodium phosphate 18.8 g
(as 24.4 g monobasic sodium phosphate dihydrate)

Dibasic sodium phosphate 4.3 g (as 10.8 g dibasic sodium phosphate dodecahydrate)

It has a sodium content of 5 g per 45 mL (11.11% w/v).

Other ingredients

It also contains purified water, glycerol, saccharin sodium, sodium benzoate (15 mg in each 45 mL dose) and ginger lemon extract 5741-5G (comprising of Oleoresin Ginger; Ethanol (Alcohol); Oil Lemon; Partially Deterpinated Oil Lemon; Citric Acid and Purified Water).

This medicine also contains very small amounts of ethanol (alcohol), less than 100mg per dose.

Distributor

PHOSPHO-SODA is distributed in Australia by:

Chiesi Australia Pty Ltd

Suite 3, 22 Gillman Street

Hawthord East VIC 3123

Email: medicalaffairs.au@chiesi.com

Website: www.chiesi.com.au

PHOSPHO-SODA is distributed in New Zealand by:

Pharmaco (NZ) Ltd, Auckland.

AUST R 283520 –

PHOSPHO-SODA oral solution bottle.

This leaflet was prepared in Oct 2021.

Phospho[®]-soda is a registered trademark of Casen Recordati, S.L.

[®] = Registered Trademark