Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fleet 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 Fleet 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 Fleet 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.

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.

This medicine is not expected to affect your ability to drive a car or operate machinery. However, it will be impractical for you to do so, as you will need to stay close to a toilet until the cleansing effect is complete.

WARNING: Serious dehydration and/or electrolyte disturbances may occur in some 'at risk' patients. Read the section, "BEFORE YOU TAKE FLEET 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.

Before you take Fleet Phospho-soda

When you must not take it

Do not take Fleet Phospho-soda if you:

- have an allergy to any of the ingredients listed at the end of this leaflet
- are under 12 years of age
- are of advanced age
- have hard, solidified bowel motions (faecal impaction)
- have non-functioning small bowel (paralytic ileus)
- have stoppage (bowel obstruction)
- have low movement of the intestines (hypomotility)
- have large bowel which was present from birth (Hirschsprung's disease/congenital megacolon)

- have the natural opening of the anus closed (imperforate anus)
- have fluid around the stomach (ascitic conditions)
- have an active inflammatory bowel disease
- have serious kidney problems
- · have congestive heart failure
- 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 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 medicines, foods, preservatives or dyes.

Tell your doctor if you:

- are in poor general health
- suffer from a heart or kidney condition
- have a colostomy
- · are on a low salt diet

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Fleet Phospho-soda.

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 Fleet Phospho-soda may interfere with each other.

These include:

- medicines which increase the volume of urine (diuretics)
- medicines used to treat some types of depressions or mood swings (lithium preparations)
- medicines which may affect electrolyte (salts in the body) levels
- 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 nflammation, including arthritis - Non-steroidal anti-inflammatory drugs (NSAIDs)

 medicines 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.

These medicines may be affected byFleet 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.

Do not take Fleet Phospho-soda at the same time as taking bowel cleansing products containing polyethylene glycol (PEG). 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 Fleet 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 in this leaflet, ask your doctor or pharmacist for help.

Do not give this medicine to children under 12 years of age.

How much to take

Adults and children 12 years of age and over: The recommended dosage is 45mL (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

The intake of *Clear liquids* is an essential part of this regimen. Please refer to *Clear liquids* list below.

First dose (1st bottle):

Take as follows:

 Mix 15mL (one third of the bottle) of Fleet Phospho-soda into a full glass (approximately 250mL) 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 250mL each) of *Clear liquids* or more if desired to prevent dehydration and to ensure that their bowel remains easily examinable for the procedure.

Second dose (2nd bottle):

Take as follows:

 Mix 15mL (one third of the bottle) of Fleet Phospho-soda into a full glass (approximately 250mL) 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 7a.m. on the day before the procedure.
- Take the second dose at 7p.m. on the evening before the procedure.

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

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

Do not eat or drink solid food, milk or milk products on the day before the procedure.

Only take *clear liquids* (see below) for breakfast, lunch and dinner and between doses the day before the procedure.

Do not drink anything coloured red or purple. 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

If you are having an operation on the bowel, you will be given your doses of Fleet 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 Fleet Phospho-soda. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Fleet Phosphosoda

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 Fleet 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 Fleet 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.

Fleet Phospho-soda may cause 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.

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

- nausea
- vomiting
- stomach pain
- bloating
- fatigue
- anal irritation
- · allergic reactions with or without rash
- hunger
- sleep loss
- feeling thirsty
- · urinating less often than normal
- dizziness

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Rare kidney disease (i.e. deposition of calcium salts within the tissues of the kidney) may also occur in some people and may be serious.

After using Fleet Phospho-soda

Storage

Keep Fleet Phospho-soda in a cool dry place where the temperature stays below $25^{\circ}C$.

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

Fleet Phospho-soda is a clear, colourless, ginger-lemon flavoured, aqueous liquid.

Ingredients

Each 45mL of Fleet Phospho-soda contains:

Active ingredients
 sodium phosphate monobasic 21.6g and
 sodium phosphate dibasic 8.1g.
 It has a sodium content of 5g per 45mL
 (11.11% w/v).

Other ingredients It also contains purified water, glycerol, saccharin sodium, sodium benzoate and ginger lemon flavour wonf 034223.

Distributor

Fleet Phospho-soda is supplied in Australia by C. B. Fleet Co (Aust) Pty Ltd

1 Rooks Road

Nunawading Vic 3131

Distributed in Australia by Ferring Pharmaceuticals P/L and New Zealand by Pharmaco (NZ) LTD

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