

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S0**

PHOLIEG 13,72 g sachet, powder for oral solution

Macrogol, sodium chloride, sodium

bicarbonate and potassium chloride

Contains artificial sweetener acesulfame potassium

Read all of this leaflet carefully because it contains important information for you

PHOLIEG is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use PHOLIEG carefully 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 see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

1. What PHOLIEG is and what it is used for

PHOLIEG is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age. PHOLIEG helps you to have a bowel movement.

2. What you need to know before you take PHOLIPEG

Do not take PHOLIPEG:

- if you are allergic (hypersensitive) to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of PHOLIPEG (listed in section 6).
- if you have a blockage in your intestine (gut obstruction, ileus).
- if you have a perforated gut wall.
- if you have severe inflammatory bowel disease like ulcerative colitis, Crohn's disease or toxic megacolon.
- if your child is below 12 years.

Warnings and precautions

Take special care with PHOLIPEG:

- if you have stomach ache, feel nauseous or are vomiting.

Consult your doctor before taking PHOLIPEG if you notice a sudden change in your bowel habits that persists for a period longer than 2 weeks.

Consult your doctor if you experience rectal bleeding or do not have a bowel movement after taking PHOLIPEG.

Do not use PHOLIPEG frequently or for long periods as this may cause dependence and a loss of normal bowel function.

If you experience symptoms such as shortness of breath, swelling, tiredness, you should stop taking PHOLIPEG and consult with your doctor.

When taking PHOLIPEG you should continue to take plenty of fluids. The fluid content of PHOLIPEG should not replace your regular liquid intake.

Other medicines and PHOLIPEG

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines, e.g. anti-epileptics, may not work as effectively during use with PHOLIEG.

PHOLIEG with, food, drink and alcohol

PHOLIEG can be taken at any time with or without food or drink.

It is recommended to take PHOLIEG before a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

PHOLIEG can be taken during pregnancy and whilst breastfeeding.

Driving and using machines

PHOLIEG does not affect your ability to drive or use machines.

PHOLIEG contains sodium

Talk to your doctor or pharmacist if you need 3 or more sachets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

PHOLIEG contains 186,87 mg sodium (main component of cooking/table salt) per sachet.

This is equivalent to 9,3 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take PHOLIEG

Do not share medicines prescribed for you with any other person.

Always take PHOLIEG exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

A dose of PHOLIEG is 1 sachet. Take this 1-3 times a day according to the severity of your constipation. The dose may be adjusted up or down, according to how hard or soft your stool

is.

When PHOLIEG is first started, it may take a few days to start working. This is because PHOLIEG works in the colon (large intestine). PHOLIEG has to travel from the mouth to the colon (on average this takes about one and a half days) and then about another day for the stools to travel from the end of the colon out of the body.

The usual dose is:

Adults: 1 sachet 1 to 3 times a day. For extended use, 1 or 2 sachets a day.

Elderly: Initially, 1 sachet a day.

If you have the impression that the effect of PHOLIEG is too strong or too weak, talk to your doctor or pharmacist.

Instructions for use:

1. Open one sachet and pour the contents of one sachet of PHOLIEG into a glass.
2. Add 125 ml (half a glass) of water.
3. Stir the mixture well until all the powder has dissolved and the PHOLIEG solution is clear or slightly hazy.
4. Drink the solution.
5. If you like you can add a flavour such as orange squash to the drink.

Duration of treatment

Treatment with PHOLIEG usually lasts for about 2 weeks.

If your constipation is caused by an illness such as Parkinson's disease or multiple sclerosis (MS) or if you take medicines that cause constipation your doctor may recommend that you take PHOLIEG for longer than 2 weeks.

If you take more PHOLIEG than you should

You may develop diarrhoea. Stop taking PHOLIEG until the diarrhoea clears. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest

hospital or poison centre.

If you forget to take PHOLIPEG

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PHOLIPEG can have side effects.

Not all side effects reported for PHOLIPEG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PHOLIPEG, please consult your health care provider for advice.

If any of the following happens, stop taking PHOLIPEG and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to PHOLIPEG. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- if you feel weak, breathless, very thirsty with a headache or get puffy ankles.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- allergic reactions which may cause a skin rash, itching, reddening of the skin or a nettle rash,

- swollen hands, feet or ankles,
- headaches,
- high and low levels of potassium in the blood,
- indigestion, stomach ache or rumbles.
- feel bloated,
- suffer from wind,
- feel sick or vomit,
- soreness of the anus (bottom),
- mild diarrhoea.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PHOLIPEG.

5. How to store PHOLIPEG

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not use after the expiry date stated on the sachet or carton.
- Once you have made up PHOLIPEG in water to form the reconstituted solution, and if you cannot drink it straight away, keep it covered and store it in the fridge (2 - 8 °C).
- Throw away any solution not used within a 24 hour period.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PHOLIPEG contains

The active substances are macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride.

Each 13,72 g sachet of PHOLIPEG powder contains:

13,125 g of macrogol 3350, 0,3507 g sodium chloride, 0,1785 g sodium bicarbonate, and 0,0466 g potassium chloride.

When PHOLIPEG powder is made into a drink with 125 ml of water each sachet gives the equivalent of:

Sodium	65 mmol/l,
Chloride	53 mmol/l,
Potassium	5,4 mmol/l and
Bicarbonate	17 mmol/l.

The other ingredients in PHOLIPEG are lemon flavouring, and acesulfame potassium as a sweetener.

What PHOLIPEG looks like and contents of the pack

PHOLIPEG is a white crystalline powder in single-dose sachets with lemon odour.

PHOLIPEG 13,72 g powder for oral solution is packed in polythene laminated aluminium sachets.

Sachets are packed in printed carton made of white board & proposed pack sizes are boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

02 May 2023

Registration numbers

PHOLIPEG: 53/11.5/0673

Access to the corresponding Professional Information

To follow