

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S0**

PHOLIEG HS 6,86 g sachet, powder for oral solution

Macrogol 3350, 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 HS is available without a doctor's prescription, for you to treat a mild illness.

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

1. What PHOLIEG HS is and what it is used for

PHOLIEG HS is a laxative for treating constipation in children.

2. What you need to know before you take PHOLIEG HS

Do not take PHOLIEG HS:

- if your child is allergic (hypersensitive) to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of PHOLIEG HS (listed in section 6).
- if your doctor has told you that your child has:
 - a blockage in the intestine (gut)
 - a hole or leak in the gut wall
 - severe inflammatory bowel disease, like ulcerative colitis, Crohn's disease, or toxic megacolon
 - paralysis of the bowel.

Warnings and precautions

Take special care with PHOLIEG HS:

- if your child has abdominal pain, nausea or vomiting.
- if your child has a heart problem.

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

If your child is having difficulty in breathing, swelling, and experiencing tiredness, PHOLIEG HS should be stopped and consult with the doctor.

When giving PHOLIEG HS you should continue to give your child plenty of fluids. The fluid content of PHOLIEG HS should not replace your child's regular liquid intake.

Other medicines and PHOLIEG HS

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

HS. When taking large volumes of PHOLIEPEG HS (e.g. for faecal impaction), your child should not take other medicines within one hour of taking PHOLIEPEG HS.

PHOLIEPEG HS with, food, drink and alcohol

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

It is recommended to take PHOLIEPEG HS 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.

PHOLIEPEG HS can be given during pregnancy and whilst breastfeeding.

Driving and using machines

PHOLIEPEG HS does not affect your ability to drive or use machines.

PHOLIEPEG HS contains sodium

PHOLIEPEG HS contains 93,4 mg sodium (main component of cooking/table salt) per sachet.

This is equivalent to 4,6 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take PHOLIEPEG HS

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

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

The dose of PHOLIEPEG HS depends on the age of the child and their response to treatment.

As a starting dose children aged 2 to 6 years should be given one sachet each day, and

children aged 7 to 11 should be given two sachets each day. Your doctor may tell you to increase the number of sachets given until your child has a soft bowel movement. This does not normally need more than 4 sachets given in one day.

It is not necessary to give all of the drink at one time, half the drink can be given in the morning and half in the evening. If the child gets very loose stools or diarrhoea the dose of PHOLIEG HS should be reduced by one sachet (if they are given 2 or more sachets a day) or a day's treatment missed out if they are given 1 sachet a day.

Open the sachet and put the powder into a glass, which is quarter full of water (about 62,5 ml). Stir well until all the powder is dissolved and it will be a clear and colourless solution. If you like, you can add a flavour such as orange squash to the drink. Then give it to your child to drink.

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

If you give more PHOLIEG HS than you should

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 give PHOLIEG HS

Give the missed dose as soon as you remember, if within a few hours after missing a dose. Do not give a double dose to make up for forgotten individual doses.

4. Possible side effects

PHOLIEG HS can have side effects.

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

If any of the following happens, stop taking PHOLIPEG HS 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 HS. 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:

Frequent:

- stomach pains,
- stomach rumbles,
- diarrhoea,
- vomiting (being sick),
- nausea (feeling sick),
- anal discomfort (uncomfortable sensation around the bottom).

Less frequent:

- swollen stomach,
- wind,
- allergic reactions, which may include, breathlessness or difficulty in breathing.

Frequency unknown:

- skin rash (hives), itching, reddening of the skin or a nettle rash, swollen hands, feet or ankles,

- headaches,
- indigestion,
- high or low levels of potassium in the blood.

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 HS.

5. How to store PHOLIPEG HS

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 HS in water to form the reconstituted solution, and if your child 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 HS contains

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

Each sachet of 6,86 g of powder contains the active substances:

Macrogol 3350	6,563 g
Sodium chloride	0,1754 g
Sodium hydrogen carbonate	0,0893 g
Potassium chloride	0,0251 g

When PHOLIPEG HS powder is made into a drink with 62,5 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 HS are lemon flavouring, and acesulfame potassium as a sweetener.

What PHOLIPEG HS looks like and contents of the pack

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

PHOLIPEG HS 6,86 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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Access to the corresponding Professional Information

To follow