Suliman Anisa Suliman - Approved - 11/08/2023

10689

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

PHOLIPEG 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
PHOLIPEG HS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use PHOLIPEG 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 PHOLIPEG HS is and what it is used for
2. What you need to know before you take PHOLIPEG HS
3. How to take PHOLIPEG HS
4. Possible side effects
5. How to store PHOLIPEG HS
6. Contents of the pack and other information

1. What PHOLIPEG HS is and what it is used for
PHOLIPEG HS is a laxative for treating constipation in children.

2. What you need to know before you take PHOLIPEG HS
Do not take PHOLIPEG HS:
- if your child is allergic (hypersensitive) to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of PHOLIPEG 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 PHOLIPEG HS:
- if your child has abdominal pain, nausea or vomiting.
- if your child has a heart problem.

Do not give PHOLIPEG 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, PHOLIPEG HS should be stopped and consult with the doctor.

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

Other medicines and PHOLIPEG HS
Always tell your healthcare 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 PHOLIPEG HS. When taking large volumes of PHOLIPEG HS (e.g. for faecal impaction), your child should not take other medicines within one hour of taking PHOLIPEG HS.

PHOLIPEG HS with, food, drink and alcohol
PHOLIPEG HS can be taken at any time with or without food or drink.
It is recommended to take PHOLIPEG 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 healthcare provider for advice before taking this medicine.

PHOLIPEG HS can be given during pregnancy and whilst breastfeeding.

Driving and using machines
PHOLIPEG HS does not affect your ability to drive or use machines.

PHOLIPEG HS contains sodium
PHOLIPEG 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 PHOLIPEG HS
Do not share medicines prescribed for you with any other person.
Always take PHOLIPEG HS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose of PHOLIPEG 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 PHOLIPEG 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 PHOLIPEG HS is too strong or too weak, talk to your doctor or pharmacist.

If you give more PHOLIPEG HS than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to give PHOLIPEG 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
PHOLIPEG HS can have side effects.
Not all side effects reported for PHOLIPEG HS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PHOLIPEG HS, please consult your healthcare 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	0,0233 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
STRIDES PHARMA SA (PTY) LTD
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Building 2
Midrand
South Africa
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This leaflet was last revised in
February 2023

Registration numbers
PHOLIPEG HS: 53/11.5/0675

Access to the corresponding Professional Information
www.trinitypharma.co.za

10689

180 x 300 mm

Front Page

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S0

PHOLIPEG HS 6,86 g sakkie, poeier vir orale oplossing
Makrogol 3350, natriumchloried, natriumbikarbonaat en kaliumchloried
Bevat kunsmatige versoeter asesulfaam kalium

Lees hierdie hele pamflet deeglik deur, aangesien dit belangrike inligting vir u bevat
PHOLIPEG HS is sonder 'n doktersvoorskrif beskikbaar, sodat u 'n ligte siekte kan behandel. U sal nogtans PHOLIPEG HS met sorg moet gebruik om die beste resultate daarmee te behaal.
- Hou hierdie pamflet. Dit is moontlik dat u dit weer sal wil lees.
- Vra u apteker indien u meer inligting of advies benodig.
- U moet 'n dokter sien indien u simptome vererger of nie na 7 dae verbeter nie.

Wat in hierdie pamflet is

1. Wat PHOLIPEG HS is en waarvoor dit gebruik word
2. Wat u moet weet voordat u PHOLIPEG HS neem
3. Hoe om PHOLIPEG HS te neem
4. Moontlike newe-effekte
5. Hoe om PHOLIPEG HS te bêre
6. Inhoud van die verpakking en ander inligting.

1. Wat PHOLIPEG HS is en waarvoor word dit gebruik
PHOLIPEG HS is 'n lakseermiddel vir die behandeling van hardlywigheid by kinders.

2. Wat u moet weet voordat u PHOLIPEG HS neem
Moet nie PHOLIPEG HS neem:
- indien u kind allergies (hipersensitief) is vir makrogol, natriumchloried, natriumbikarbonaat, kaliumchloried of enige van die ander bestanddele van PHOLIPEG HS (gelys in afdeling 6).
- indien u dokter vir u gesê het dat u kind die volgende het:
  - 'n verstopping in die ingewande (derm)
  - 'n gat of lek het in die dermwand
  - ernstige inflammatoriese dermsiekte het soos ulseratiewe kolitis, Crohn se siekte of toksiese megakolon
  - verlamming van die derm.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met PHOLIPEG HS:
- indien u kind maagpyn het, naar voel of braak.
- indien u kind 'n hartprobleem het.

Moet nie PHOLIPEG HS gereeld of vir lang periodes gee nie, aangesien dit afhanklikheid en 'n verlies van normale dermfunksie kan veroorsaak.

Indien u kind sukkel om asem te haal, opswel, en moegheid ervaar, moet PHOLIPEG HS gestaak word en die dokter geraadpleeg word.

Wanneer PHOLIPEG HS gegee word, moet u aanhou om u kind baie vloeistowwe te gee. Die vloeistofinhoud van PHOLIPEG HS moet nie u kind se gereelde vloeistofinname vervang nie.

Ander medisyne en PHOLIPEG HS
Noem altyd aan u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit komplimentêre of tradisionele medisyne in).

Sommige medisyne, bv. anti-epileptiese middels, werk moontlik nie so effektief tydens gebruik van PHOLIPEG HS nie. Wanneer groot volumes PHOLIPEG HS geneem word (bv. vir fekale impaksie), moet u kind nie binne 'n uur na die inname van PHOLIPEG HS ander medisyne gebruik nie.

PHOLIPEG HS met voedsel, drank en alkohol
PHOLIPEG HS kan enige tyd geneem word met of sonder kos of drank.
Dit word aanbeveel om PHOLIPEG HS voor 'n ete te neem.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

PHOLIPEG HS kan tydens swangerskap en tydens borsvoeding geneem word.

Bestuur en gebruik van masjinerie
PHOLIPEG HS beïnvloed nie u vermoë om te bestuur of masjinerie te gebruik nie.

PHOLIPEG HS bevat natrium
PHOLIPEG HS bevat 93,4 mg natrium (hoofbestanddeel van kook-/tafelsout) per sakkie. Dit is gelykstaande aan 4,6 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

3. Hoe om PHOLIPEG HS te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem PHOLIPEG HS altyd presies soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Die dosis PHOLIPEG HS hang af van die kind se ouderdom en hul response op behandeling. As 'n aanvangsdosis moet kinders van 2 tot 6 jaar een sakkie elke dag gegee word, en kinders van 7 tot 11 jaar twee sakkies elke dag. U dokter mag dalk vir u sê om die aantal sakkies te verhoog totdat u kind sagte opelyf het. Dit vereis gewoonlik nie meer as 4 sakkies in een dag nie.

Dit is nie nodig om die hele drankie op een slag te gee nie, helfte van die drankie kan soggens en helfte kan saans gegee word. Indien die kind baie los stoelgange of diarree kry, moet die PHOLIPEG HS-dosis met een sakkie verminder word (indien hulle 2 of meer sakkies per dag kry) of 'n dag se behandeling moet oorgeslaan word indien hulle 1 sakkie per dag kry.

Maak die sakkie oop en gooi die poeier in 'n glas in wat kwartvol water (ongeveer 62,5 ml) is. Roer goed totdat al die poeier opgelos het en dit sal dan 'n helder en kleurlose oplossing wees. Indien u wil, kan u 'n geursel byvoeg, soos lemoensap. Gee dit dan vir u kind om te drink.

Indien u die indruk kry dat die effek van PHOLIPEG HS te sterk of te swak is, praat met u dokter of apteker.

Indien u meer PHOLIPEG HS gee as wat u moet
In geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u vergeet om PHOLIPEG HS te gee
Gee die vergete dosis sodra u onthou, indien dit binne 'n paar uur is wat u die dosis vergeet het. Moet nie 'n dubbele dosis gee om die vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte
PHOLIPEG HS kan newe-effekte hê.
Nie alle newe-effekte wat vir PHOLIPEG HS gerapporteer is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of indien u onaangename effekte ervaar tydens die gebruik van PHOLIPEG HS, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, stop om PHOLIPEG HS te neem en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling in u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, tong en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak.

Hierdie is almal baie ernstige newe-effekte. Indien u dit ondervind, het u moontlik 'n ernstige reaksie teen PHOLIPEG HS. U mag dalk dringende mediese hulp of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle-afdeling in u naaste hospitaal indien u enige van die volgende opmerk:
- indien u swak, uitasem, baie dors voel met hoofpyn of geswelde enkels.

Hierdie is almal ernstige newe-effekte. U mag dalk dringende mediese hulp benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Gereeld
- maagpyn,
- buikrommeling,
- diarree,
- braking (siek wees),
- naarheid (siek gevoel),
- anale ongemak (ongemaklike gevoel rondom die boud).

Minder gereeld:
- opgeblaasde maag,
- winderigheid,
- allergiese reaksies wat asemnood of asemhalingsprobleme kan insluit.

Frekwensie onbekend:
- veluitslag (konwe), jeuk, rooiwording van die vel of 'n brandende uitslag, geswelde hande, voete of enkels,
- hoofpyn,
- sooibrand,
- hoë of lae kaliumvlakke in die bloed.

Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem is nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter of apteker. U kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting in te win oor die veiligheid van PHOLIPEG HS.

5. Hoe om PHOLIPEG HS te bêre
Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 25 °C.
- Moet nie gebruik na die vervaldatum wat op die sakkie of karton aangedui is nie.
- Sodra u PHOLIPEG HS in water aangemaak het om die gerekonstitueerde oplossing te vorm, en u kind dit nie dadelik kan drink nie, hou dit bedek en bêre dit in die yskas (2 - 8 °C).
- Gooi enige oplossing weg wat nie binne 24 uur gebruik is nie.

Neem alle ongebruikte medisyne terug na u apteker
Moet nie ongebruikte medisyne in dreine of rioolstelsels wegdoen nie (bv. toilette).

6. Inhoud van die verpakking en ander inligting
Wat PHOLIPEG HS bevat
Die aktiewe bestanddele is makrogol 3350, natriumchloried, natriumbikarbonaat en kaliumchloried.

Elke sakkie van 6,86 g poeier bevat die aktiewe stowwe:

Makrogol 3350	6,563 g
Natriumchloried	0,1754 g
Natriumbikarbonaat	0,0893 g
Kaliumchloried	0,0233 g

Wanneer PHOLIPEG HS poeier in 'n drankie opgemaak word met 62,5 ml water, gee elke sakkie die ekwivalent van:

Natrium	65 mmol/l,
Chloried	53 mmol/l,
Kalium	5,4 mmol/l en
Bikarbonaat	17 mmol/l.

Die ander bestanddele in PHOLIPEG HS is suurlemoen geursel, en asesulfaam kalium as 'n versoeter.

Hoe PHOLIPEG HS lyk en die inhoud van die pak
PHOLIPEG HS is 'n wit kristallyne poeier in enkeldosis-sakkies met suurlemoengeur. PHOLIPEG HS 6,86 g poeier vir orale oplossing word verpak in politeen gelamineerde aluminium sakkies.

Sakkies word verpak in gedrukte karton gemaak van wit karton & voorgestelde verpakkingsgroottes is boksies van 6, 8, 10, 20, 30, 40, 50, 60 of 100 sakkies.
Nie alle verpakkingsgroottes mag moontlik bemark word nie.

Houer van Registrasiesertifikaat
STRIDES PHARMA SA (PTY) LTD
106 16de Weg
Gebou 2
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1685

Hierdie pamflet was laas opgedateer in
Februarie 2023

Registrasie nommers
PHOLIPEG HS: 53/11.5/0675

Toegang tot die ooreenstemmende Professionele inligting
www.trinitypharma.co.za

10690

1049358

10690

180 x 300 mm

Back Page

NON PRINTING COLOURS

ARTWORK DETAIL LABEL

Mfg Location: KRSG

Product	**PHOLIPEG HS (Macrogol 6.86g)**				
Buyer/Country	South Africa	Component	Pack Insert		
Dimension	**180 x 300 mm**			Pack	-
New Item Code	**1049358**	Old Item Code	NA		
Colour Shades	Black			No. of Colours	1

Change Control No.	PC-ODF/2023/490 - Record Number: 389455	Artwork Version	1.0
Design/Style	Front & Back Printing. To be supplied in folded size: 90 x 75 mm		
Substrate	60 GSM Maplitho Paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	NA		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

RD/PD/003/F-08/R0