Suliman Anisa Suliman - Approved - 11/08/2023

10691

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S0

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

1. What PHOLIPEG is and what it is used for
PHOLIPEG is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age. PHOLIPEG 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 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.

PHOLIPEG with, food, drink and alcohol
PHOLIPEG can be taken at any time with or without food or drink.
It is recommended to take PHOLIPEG 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 can be taken during pregnancy and whilst breastfeeding.

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

PHOLIPEG 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.
PHOLIPEG 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 PHOLIPEG
Do not share medicines prescribed for you with any other person.
Always take PHOLIPEG exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
A dose of PHOLIPEG 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 PHOLIPEG is first started, it may take a few days to start working. This is because PHOLIPEG works in the colon (large intestine). PHOLIPEG 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 PHOLIPEG 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 PHOLIPEG 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 PHOLIPEG 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 PHOLIPEG 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 PHOLIPEG for longer than 2 weeks.

If you take more PHOLIPEG than you should
You may develop diarrhoea. Stop taking PHOLIPEG until the diarrhoea clears. 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 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 healthcare 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
STRIDES PHARMA SA (PTY) LTD
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Registration numbers
PHOLIPEG: 53/11.5/0673

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

10691

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S0

PHOLIPEG 13,72 g sakkie, poeier vir orale oplossing
Makrogol, natriumchloried, natriumbikarbonaat en kaliumchloried
Bevat kunsmatige versoeter asesulfaam kalium

Lees hierdie hele pamflet deeglik deur, aangesien dit belangrike inligting vir u bevat
PHOLIPEG is sonder 'n doktersvoorskrif beskikbaar, sodat u 'n ligte siekte kan behandel. U sal nogtans PHOLIPEG 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 is en waarvoor dit gebruik word
2. Wat u moet weet voordat u PHOLIPEG neem
3. Hoe om PHOLIPEG te neem
4. Moontlike newe-effekte
5. Hoe om PHOLIPEG te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat PHOLIPEG is en waarvoor word dit gebruik
PHOLIPEG is 'n lakseermiddel vir die behandeling van hardlywigheid by volwassenes, adolessente en bejaardes. Dit word nie aanbeveel vir kinders jonger as 12 jaar nie. PHOLIPEG help u om opelyf te hê.

2. Wat u moet weet voordat u PHOLIPEG neem
Moet nie PHOLIPEG neem:
- indien u allergies (hipersensitief) is vir makrogol, natriumchloried, natriumbikarbonaat, kaliumchloried of enige van die ander bestanddele van PHOLIPEG (gelys in afdeling 6).
- indien u 'n verstopping in u ingewande het (dermobstruksie, ileus).
- indien u 'n geperforeerde dermwand het.
- indien u 'n ernstige inflammatoriese dermsiekte het soos ulseratiewe kolitis, Crohn se siekte of toksiese megakolon.
- indien u kind jonger as 12 jaar is.

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

Raadpleeg u dokter voordat u PHOLIPEG neem indien u 'n skielike verandering in u opelyf-gewoontes sien wat langer as 2 weke aanhou.
Raadpleeg u dokter indien u rektale bloeding ervaar of nie opelyf het nadat u PHOLIPEG geneem het nie.
Moet nie PHOLIPEG gereeld of vir lang periodes gebruik nie, aangesien dit afhanklikheid en 'n verlies aan normale dermfunksie kan veroorsaak.
Indien u simptome soos kortasem, swelling, moegheid ervaar, moet u ophou om PHOLIPEG te neem en u dokter raadpleeg.
Terwyl u PHOLIPEG neem, moet u baie vloeistowwe inneem. Die vloeistofinhoud van PHOLIPEG moet nie u gereelde vloeistofinname vervang nie.

Ander medisyne en PHOLIPEG
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 nie.

PHOLIPEG met voedsel, drank en alkohol
PHOLIPEG kan enige tyd geneem word met of sonder kos of drank.
Dit word aanbeveel om PHOLIPEG 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 kan tydens swangerskap en tydens borsvoeding geneem word.

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

PHOLIPEG bevat natrium
Praat met u dokter of apteker indien u 3 of meer sakkies per dag vir 'n lang tydperk benodig, veral indien u 'n lae-sout (natrium) dieet moet volg.
PHOLIPEG bevat 186,87 mg natrium (hoofbestanddeel van kook-/tafelsout) per sakkie. Dit is gelykstaande aan 9,3 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

3. Hoe om PHOLIPEG te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem PHOLIPEG altyd presies soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.
'n Dosis PHOLIPEG is 1 sakkie. Neem dit 1-3 keer per dag, afhangende van die erns van u hardlywigheid. Die dosis kan verhoog of verlaag word, afhangende van hoe hard of sag u stoelgang is.
Wanneer PHOLIPEG vir die eerste keer begin word, kan dit 'n paar dae neem om te begin werk. Dit is omdat PHOLIPEG in die kolon (dikderm) werk. PHOLIPEG moet van die mond na die dikderm beweeg (gemiddeld neem dit ongeveer een en 'n halwe dae) en dan ongeveer nog 'n dag vir die stoelgang om van die einde van die kolon uit die liggaam te beweeg.
Die gewone dosis is:
Volwassenes: 1 sakkie 1 tot 3 keer per dag. Vir langdurige gebruik, 1 of 2 sakkies per dag.
Bejaardes: Aanvanklik 1 sak per dag.
Indien u die indruk kry dat die effek van PHOLIPEG te sterk of te swak is, praat met u dokter of apteker.

Gebruiksaanwysings:
1. Maak een sakkie oop en gooi die inhoud van een sakkie PHOLIPEG in 'n glas.
2. Voeg 125 ml (half glas) water by.
3. Roer die mengsel goed totdat al die poeier opgelos het en die PHOLIPEG oplossing helder of effens troebel is.
4. Drink die oplossing.
5. Indien u wil, kan u 'n geursel byvoeg, soos lemoensap.

Duur van behandeling
Behandeling met PHOLIPEG duur gewoonlik ongeveer 2 weke.
Indien u hardlywigheid veroorsaak word deur 'n siekte soos Parkinson se siekte of veelvuldige sklerose (VS) of indien u medisyne neem wat hardlywigheid veroorsaak, mag u dokter moontlik aanbeveel dat u PHOLIPEG vir langer as 2 weke moet neem.

Indien u meer PHOLIPEG neem as wat u moet
U mag dalk diarree ontwikkel. Hou op om PHOLIPEG te neem totdat die diarree opklaar. 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 te neem
Moet nie 'n dubbele dosis neem om die vergete individuele dosisse op te maak nie.

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

Indien enige van die volgende gebeur, stop om PHOLIPEG 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. 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:
Frekwensie onbekend:
- allergiese reaksies wat 'n veluitslag, jeuk, rooiheid van die vel of 'n brandende uitslag kan veroorsaak,
- geswelde hande, voete of enkels,
- hoofpyn,
- hoë en lae kaliumvlakke in die bloed,
- sooibrand, maagpyn of buikrommeling,
- opgeblase gevoel,
- aan winderigheid ly,
- siek gevoel of braking,
- pyn in die anus (boud),
- ligte diarree.

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.*

5. Hoe om PHOLIPEG 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 in water aangemaak het om die gerekonstitueerde oplossing te vorm, en u 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 bevat
Die aktiewe bestanddele is makrogol 3350, natriumchloried, natriumbikarbonaat en kaliumchloried.
Elke 13,72 g sakkie PHOLIPEG poeier bevat:
13,125 g makrogol 3350, 0,3507 g natriumchloried, 0,1785 g natriumbikarbonaat en 0,0466 g kaliumchloried.
Wanneer PHOLIPEG poeier in 'n drankie opgemaak word met 125 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 is suurlemoen geursel, en asesulfaam kalium as 'n versoeter.

Hoe PHOLIPEG lyk en die inhoud van die pak
PHOLIPEG is 'n wit kristallyne poeier in enkeldosis-sakkies met suurlemoengeur.
PHOLIPEG 13,72 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
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Hierdie pamflet was laas opgedateer in
Mei 2023

Registrasie nommers
PHOLIPEG: 53/11.5/0673

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

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180 x 300 mm — Front Page

180 x 300 mm — Back Page

NON PRINTING COLOURS

ARTWORK DETAIL LABEL

Mfg Location: KRSG

Product	**PHOLIPEG (Macrogol 13.72g)**				
Buyer/Country	South Africa	Component	Pack Insert		
Dimension	**180 x 300 mm**			Pack	-
New Item Code	**1049361**	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