

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S0**

PHYGLETON 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

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

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

1. What PHYGLETON is and what it is used for

PHYGLETON is a laxative for the treatment of constipation in adults, adolescents and elderly.

It is not recommended for children below 12 years of age. PHYGLETON helps you to have a bowel movement.

2. What you need to know before you take PHYGLETON

Do not take PHYGLETON:

- if you are allergic (hypersensitive) to macrogol, sodium chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of PHYGLETON (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 PHYGLETON:

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

Consult your doctor before taking PHYGLETON 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 PHYGLETON.

Do not use PHYGLETON 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 PHYGLETON and consult with your doctor.

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

Other medicines and PHYGLETON

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 PHYGLETON.

PHYGLETON with, food, drink and alcohol

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

It is recommended to take PHYGLETON 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.

PHYGLETON can be taken during pregnancy and whilst breastfeeding.

Driving and using machines

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

PHYGLETON 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.

PHYGLETON 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 PHYGLETON

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

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

A dose of PHYGLETON 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 PHYGLETON is first started, it may take a few days to start working. This is because PHYGLETON works in the colon (large intestine). PHYGLETON 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 PHYGLETON 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 PHYGLETON 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 PHYGLETON 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 PHYGLETON 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 PHYGLETON for longer than 2 weeks.

If you take more PHYGLETON than you should

You may develop diarrhoea. Stop taking PHYGLETON 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 PHYGLETON

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

4. Possible side effects

PHYGLETON can have side effects.

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

If any of the following happens, stop taking PHYGLETON 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 PHYGLETON. 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 PHYGLETON.

5. How to store PHYGLETON

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 PHYGLETON 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 PHYGLETON contains

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

Each 13,72 g sachet of PHYGLETON 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 PHYGLETON 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 PHYGLETON are lemon flavouring, and acesulfame potassium as a sweetener.

What PHYGLETON looks like and contents of the pack

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

PHYGLETON 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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Access to the corresponding Professional Information

To follow