1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

PEGICOL PLAIN 6,9 g powder for reconstitution

Macrogol 3 350

Potassium chloride

Sodium bicarbonate

Sodium chloride

Sugar free

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

PEGICOL PLAIN is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PEGICOL PLAIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PEGICOL PLAIN with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What PEGICOL PLAIN is and what it is used for
2. What you need to know before you take PEGICOL PLAIN

3. How to use PEGICOL PLAIN
4. Possible side effects
5. How to store PEGICOL PLAIN
6. Contents of the pack and other information

1. What PEGICOL PLAIN is and what it is used for

PEGICOL PLAIN belongs to a group of medicines called laxatives for treating constipation in children.

2. What you need to know before you give PEGICOL PLAIN

Do not give PEGICOL PLAIN

- if your child is hypersensitive (allergic) to macrogol (PEG), sodium bicarbonate, sodium chloride, potassium chloride or any of the other ingredients of PEGICOL PLAIN (listed in section 6).
- if your child is under the age of 2 years.
- 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 PEGICOL PLAIN:

- if your child has a heart or kidney problem, you should talk to your doctor before giving PEGICOL PLAIN.
- if patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure), PEGICOL PLAIN should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.
- if there is a sudden change in bowel habits that has persisted for a period greater than 2 weeks; a medical practitioner should be consulted.
- rectal bleeding or failure to have a bowel movement after use of PEGICOL PLAIN may indicate a serious underlying condition. PEGICOL PLAIN should be discontinued and medical advice obtained.
- PEGICOL PLAIN should not be used in the presence of abdominal pain, nausea or vomiting.

- PEGICOL PLAIN should not be used continuously. Frequent or prolonged use of laxatives, such as PEGICOL PLAIN may result in dependence and loss of normal bowel function

Children and adolescents

Not recommended for children below two years old.

Other medicines with PEGICOL PLAIN

Always tell your healthcare provider about any other medicines your child is taking (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Anti-epileptics. medicines used to treat epilepsy.
- PEGICOL PLAIN raises the solubility of medicines that are soluble in alcohol and relatively insoluble in water.
- There is a possibility that the absorption of other medicines could be reduced during use with PEGICOL PLAIN and might not work as well.

Pregnancy, breastfeeding and fertility

There are limited amount of data from the use of PEGICOL PLAIN in pregnant women.

Driving and using machines

Your child should not use machinery or perform any tasks that require concentration until you are certain that PEGICOL PLAIN does not adversely affect their ability to do so safely (see section 4).

3. How to give PEGICOL PLAIN

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

Always take PEGICOL PLAIN exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual starting dose is:

Children aged 2 to 6 years: 1 sachet daily.

Children aged 7 to 11 years: 2 sachets a day.

The dose of PEGICOL PLAIN depends on the age of the child and their response to treatment. Your doctor may tell you to increase or decrease 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, if the child prefers it, half the dose can be given in the morning and half in the evening. If the child gets very loose stools or diarrhoea the dose of PEGICOL PLAIN 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.

Your doctor will tell you how long your treatment with PEGICOL PLAIN will last. Do not stop treatment early. If you have the impression that the effect of PEGICOL PLAIN is too strong or too weak, tell your doctor or pharmacist.

If you give more PEGICOL PLAIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to give PEGICOL PLAIN

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

4. Possible side effects

Not all side effects reported for PEGICOL PLAIN are included in this leaflet. Should your child's general health worsen or if they experience any untoward effects while taking PEGICOL PLAIN, please consult your healthcare provider for advice.

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PEGICOL PLAIN. 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:

- Muscle weakness, twitching or abnormal heart rhythm.

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

Side effects with an unknown frequency

- headache,
- stomach pain, stomach cramps, diarrhoea (frequent/loose watery stools), vomiting (being sick), nausea (feeling sick), dyspepsia (heartburn, indigestion), feeling bloated, stomach rumbles, flatulence, anus and rectum discomfort, peripheral oedema (accumulation of fluid causing swelling usually in the lower limbs).

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, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of PEGICOL PLAIN.

5. How to store PEGICOL PLAIN

Store all medicine out of reach of children.

Store at or below 25 °C.

The reconstituted solution should be taken immediately or stored at 2 °C to 8 °C (refrigerated and covered) for not longer than 24 hours.

Keep in the original packaging until required for use. Do not use PEGICOL PLAIN after the expiry date stated on the label.

Do not store in a bathroom.

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

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

Each sachet of 6,9 g of powder contains the active substances:

Macrogol 3 350 6,563 g

Potassium chloride	25,1 mg
Sodium bicarbonate	89,3 mg
Sodium chloride	175,4 mg

Sugar free

What PEGICOL PLAIN looks like and contents of the pack

PEGICOL PLAIN is a white, free-flowing, crystalline powder. When the powder is completely dissolved in a quarter glass of water the solution is clear and colourless.

Cartons containing 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

White sachets are sealed together in pairs with a perforated strip between them to allow for the separation of each sachet. Each carton contains 2, 6, 8, 10, 20, 30, 60, 100 sachets that are packed into a printed cardboard carton, with a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information

Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

BOTSWANA: BOT1101827 S3

NAMIBIA: NS2 13/11/0081

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