PATIENT INFORMATION LEAFLET FOR

PURGOLENE

Scheduling Status

S0

PURGOLENE (13,8 g powder for oral solution)

Macrogol 3350

Sodium bicarbonate

Sodium chloride

Potassium chloride

Sugar free

Contains sweetener (acesulfame potassium): 75 mg per sachet

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

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

Nevertheless, you still need to use PURGOLENE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PURGOLENE with any other person.
- Ask your health care provider or 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 PURGOLENE is and what it is used for

2. What you need to know before you take PURGOLENE
3. How to take PURGOLENE
4. Possible side effects
5. How to store PURGOLENE
6. Contents of the pack and other information.

1. What PURGOLENE is and what it is used for

PURGOLENE is a laxative for the treatment of constipation in adults, adolescents and elderly. It is not recommended for children below 12 years of age.

PURGOLENE helps you to have a bowel movement even if you have been constipated for a long time.

2. What you need to know before you take PURGOLENE

Do not take PURGOLENE:

- if you are hypersensitive (allergic) to macrogol, sodium, chloride, sodium bicarbonate, potassium chloride or any of the other ingredients of PURGOLENE (listed in **section 6**).
- if you have a blockage in your gut (symptoms may include sever stomach pain, nausea, vomiting and an inability to pass wind or stools)
- if you have a perforated (ruptured) gut wall (with symptoms such as severe stomach pain and tenderness)
- if you have severe inflammatory bowel disease like ulcerative colitis (chronic disease affecting the large bowel), Crohn's disease (inflammation of last part of small bowel) or toxic megacolon (potentially lethal complication of inflammatory bowel disease or infectious colitis that is characterized by an abnormal dilation of the large intestine).

- if you have ileus (paralysis of the intestines with symptoms such as stomach cramps, bloating, nausea, vomiting, constipation, difficulty passing wind and difficulty tolerating a normal diet).
- if you have gastric retention (symptoms generally include nausea, vomiting, bloating, and upper abdominal discomfort).
- if you have peptic ulceration (a sore that develops on the lining of the oesophagus, stomach or small intestine with symptoms such as upper abdominal pain).
- if you are under 12 years of age.

Warnings and Precautions

PURGOLENE does not replace regular fluid intake and adequate fluid intake must be maintained.

If you have stomachache, feel nauseous or are vomiting.

Consult your doctor before using PURGOLENE if you notice a sudden change in bowel habits that persists for longer than 2 weeks.

Consult your doctor if you experience rectal bleeding or do not have a bowel movement after using PURGOLENE.

Do not use PURGOLENE frequently or continuously as this may cause dependence and a loss of normal bowel function.

Children and adolescents

Not recommended for children below 12 years old.

Other medicines and PURGOLENE

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

- Anti-epileptics: medicines used to treat epilepsy
- PURGOLENE 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 PURGOLENE and might not work as well.

If you are taking other medicines on a regular basis, the use of PURGOLENE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

PURGOLENE with food, drink and alcohol

PURGOLENE can be taken with or without food or drink. It is recommended to take PURGOLENE before a meal.

Pregnancy, breastfeeding and fertility

PURGOLENE can be taken during pregnancy and whilst breastfeeding.

If you are pregnant or breastfeeding your baby, 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 PURGOLENE.

Driving and using machines

It is not always possible to predict to what extent PURGOLENE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PURGOLENE affects them.

PURGOLENE is not expected to affect your ability to drive and use machines.

3. How to take PURGOLENE

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

Always take PURGOLENE exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

A dose of PURGOLENE is 1 sachet. Take these 1 to 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 PURGOLENE is first started, it may take a few days to start working. This is because PURGOLENE works on the colon (large intestine). PURGOLENE has to travel from the mouth to the colon (on average this takes about 1 ½ days) and then about another day for the stool 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 one sachet per day.

Children (below 12 years old): not recommended.

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

Instructions for use

1. Open one sachet and pour the contents into a glass.
2. Add 125 ml (½ glass) of water.
3. Stir the mixture well until all the powder has dissolved and the PURGOLENE oral solution is slightly hazy or clear.
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 PURGOLENE 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 medicine that cause constipation, your doctor may recommend that you take PURGOLENE for longer than 2 weeks.

If you take more PURGOLENE than you should

You may develop diarrhoea. Stop taking PURGOLENE until the diarrhoea clears.

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

If you forget to take PURGOLENE

Take the dose as soon as you remember to take it.

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

4. Possible Side Effects

PURGOLENE can have side effects**.**

Not all side effects reported for PURGOLENE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PURGOLENE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PURGOLENE 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 PURGOLENE. 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:

- hyperkalemia (too much potassium in the blood which can cause abnormal heart rhythm); hypokalaemia (low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm)

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

Tell your doctor if you notice any of the following:

Side effects with 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 via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or

by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of PURGOLENE.

5. How to store PURGOLENE

- Store at or below 25 °C.
- Do not use after the expiry date on the sachet and carton.
- Once you have dissolved PURGOLENE in water to form the solution and if you cannot drink it straight away, keep it covered and store it in the fridge (2 ºC to 8 ºC). Throw away any solution not used within a 24-hour period.
- Store all medicines out of reach of children
- 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 PURGOLENE contains

The active substances are 13,125 g of macrogol (PEG), 178,5 mg of sodium bicarbonate, 350,7 mg of sodium chloride and 46,6 mg of potassium chloride.

When PURGOLENE 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
Bicarbonate	17 mmol/l

The other ingredients are in PURGOLENE are acesulfame potassium as a sweetener and lemon flavouring. It contains no sugar.

Contains sweetener: acesulfame potassium 75 mg.

What PURGOLENE looks like and contents of the pack

Each sachet contains a white, free flowing flaky powder with a lemon flavour and odour and a sweet taste. When dissolved in water, the solution is clear or slightly hazy when compared with an equal volume of water.

PURGOLENE is available in cartons each containing 5, 8, 10 or 20 aluminium foil sachets coated with low density polyethylene.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

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This leaflet was revised in

15/12/2022

Registration number(s)

42/11.5/0412