

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM

PURGOLENE (13,8 g sachet - Powder for oral solution)

COMPOSITION

Each 13,8 g sachet of **PURGOLENE** powder contains:

Macrogol (PEG) 3350	13,125 g
Sodium bicarbonate	178,5 mg
Sodium chloride	350,7 mg
Potassium chloride	46,6 mg

The content of electrolyte ions per sachet when made up to 125 mL of oral solution is as follows:

Sodium	65 mmol/ℓ
Chloride	53 mmol/ℓ
Potassium	5,4 mmol/ℓ
Bicarbonate	17 mmol/ℓ

Excipients:

Acesulfame potassium (E950) and lemon flavour 9021145. Contains no sugar. Contains 75,0 mg acesulfame potassium (E950) as a sweetener.

PHARMACOLOGICAL CLASSIFICATION

A 11.5 Medicines acting on the gastro-intestinal tract. Laxatives.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

PURGOLENE, an iso-osmotic laxative, is a combination of macrogol 3350 (polyethylene glycol) and electrolytes.

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol 3350 increases the stool volume, which triggers colon motility via neuromuscular pathways.

Electrolytes combined with macrogol 3350 are exchanged across the intestinal barrier (mucosa) with serum electrolytes and excreted in faecal water without net gain or loss of sodium, potassium and water.

Pharmacokinetic properties:

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract. Any macrogol 3350 that is absorbed is excreted via the urine.

The laxative action of polyethylene glycol has a time course which will vary according to the severity of the constipation being treated.

INDICATIONS

For the treatment of chronic constipation.

CONTRAINDICATIONS

Known hypersensitivity to polyethylene glycol or any of the ingredients of **PURGOLENE**.

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, gastric retention, peptic ulceration and severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis and toxic megacolon.

Safety in pregnancy has not been established.

Not recommended for children under 12 years of age.

WARNINGS AND SPECIAL PRECAUTIONS

PURGOLENE should not be used in the presence of abdominal pain, nausea or vomiting.

PURGOLENE should not be used continuously unless directed by your doctor. Frequent or prolonged use of laxatives may result in dependence and loss of normal bowel function.

If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) **PURGOLENE** 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 **PURGOLENE** may indicate a serious condition. **PURGOLENE** use should be discontinued and medical advice obtained.

Effects on ability to drive and use machines

PURGOLENE has no influence on the ability to drive and use machines.



PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

PURGOLENE (Powder for oral solution)

Read this leaflet carefully, because it contains important information.

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 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 PURGOLENE CONTAINS

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

Each 13,8 g sachet of **PURGOLENE** powder contains:

Macrogol (PEG) 3350	13,125 g
Sodium bicarbonate	178,5 mg
Sodium chloride	350,7 mg
Potassium chloride	46,6 mg

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 in **PURGOLENE** are acesulfame potassium (E950) and lemon flavour 9021145. It contains no sugar. Contains 75,0 mg acesulfame potassium (E950) as a sweetener.

WHAT PURGOLENE 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.

BEFORE YOU TAKE PURGOLENE

Do not take PURGOLENE

If you are hypersensitive to macrogol, sodium, chloride, sodium bicarbonate, potassium chloride or any of the ingredients of **PURGOLENE**.

Do not take PURGOLENE if your doctor has told you that you have

- a blockage in your intestine (gut)
- a perforated gut wall
- severe inflammatory conditions like Crohn's disease, ulcerative colitis and toxic megacolon.
- ileus (paralysis of the bowel)

Take special care with PURGOLENE

- If you have stomach ache, 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.
- Safety in pregnancy has not been established.

Taking PURGOLENE with food and drink

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby while taking **PURGOLENE**, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machines

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

Taking other medicines with PURGOLENE

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

HOW TO TAKE PURGOLENE

Always take **PURGOLENE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

A dose of **PURGOLENE** 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 **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.

INTERACTIONS

No clinical interactions with other medicinal products have been reported.

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. There is therefore a theoretical possibility that the absorption of such medicinal products could be transiently reduced during use with **PURGOLENE**.

PREGNANCY AND LACTATION

The safe use of **PURGOLENE** during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults: 1 or 3 sachets daily in divided doses, according to individual response. The powder in each sachet should be dissolved in 125 mL water and taken orally.

Elderly: Initially one sachet per day is recommended.

No dosage change is needed to be made for patients with renal insufficiency.

A course of treatment with **PURGOLENE** should normally not exceed 2 weeks, although this can be repeated if required. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medication, in particular opioids and antimuscarinics.

For extended use, the dose can be adjusted down to 1 or 2 sachets daily, in divided doses, each dissolved in 125 mL water and taken orally.

SIDE EFFECTS

Immune system disorders

Frequency unknown: Allergic reactions, including anaphylaxis and urticaria.

Gastrointestinal disorders

Frequency unknown: Abdominal pain, mild diarrhoea which usually responds to dose reduction, vomiting, nausea, abdominal distension, abdominal cramps, borborygmi, anal irritation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

(See '**SIDE EFFECTS**' and '**WARNINGS AND SPECIAL PRECAUTIONS**').

In the case of gross accidental over dosage, extensive fluid loss by diarrhoea or vomiting may require correction with generous amounts of fluid and electrolytes. Severe pain or distension associated with overdosage can be treated by nasogastric aspiration.

IDENTIFICATION

White, free flowing, flaky powder with a lemon flavour and odour and a sweet taste. When the powder is dissolved, the resultant solution is clear and colourless or slightly hazy.

PRESENTATION

Cartons containing 5, 8, 10 or 20 aluminium foil sachets coated with low density polyethylene.

STORAGE INSTRUCTIONS

Sachet: Store at or below 25 °C.

Solution: The prepared oral solution should be taken immediately and not stored.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

42/11.5/0412

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD
Building 9, Parc du Cap,
Mispel Street
Bellville
7530, RSA

DATE OF PUBLICATION OF THE PACKAGE INSERT

9 June 2016

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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.

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 medicines 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 doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to take PURGOLENE

Take the dose as soon as you remember to take it. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

PURGOLENE can have side effects.

You may experience an allergic reaction, such as a life-threatening allergic reaction called anaphylaxis. You may experience stomach ache, or have rumbles, feel bloated, sick and/or nauseous. You may have mild diarrhoea when starting to take **PURGOLENE**.

If any of the above are troublesome or last more than a few days, tell your doctor or pharmacist.

If you feel weak, breathless, very thirsty with a headache or get puffy ankles, stop taking **PURGOLENE** and tell your doctor immediately.

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

STORING AND DISPOSING OF PURGOLENE

Keep all medicines out of the reach and sight of children.

Store **PURGOLENE** 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 °C – 8 °C). Throw away any solution not used within a 24 hour period.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

PRESENTATION OF PURGOLENE

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

IDENTIFICATION OF PURGOLENE

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.

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