PROFESSIONAL INFORMATION FOR

PURGOLENE (powder for oral solution)

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

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

2. QUALITATIVE AND QUANTITATIVE 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 solution is as follows:

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

Sugar free.

Contains sweetener (acesulfame potassium): 75 mg per sachet.

For the full list of excipients, see **section 6.1**.

3. PHARMACEUTICAL FORM

Powder for oral solution.

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 when compared with an equal volume of water.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PURGOLENE is indicated for the treatment of chronic constipation.

4.2 Posology and method of administration

Posology

Adults:

1 to 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.

Children (below 12 years old): not recommended.

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.

Method of administration

For oral administration.

4.3 Contraindications

PURGOLENE is contraindicated in:

- Patients with known hypersensitivity to polyethylene glycol or any of the ingredients of PURGOLENE (see **section 6.1**).
- 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.
- Not recommended for children under 12 years of age.

4.4 Special warnings and precautions for use

The fluid content of PURGOLENE when re-constituted with water does not replace regular fluid intake and adequate fluid intake must be maintained.

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.

Adverse drug reactions are possible (see section 4.8.) 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.

The absorption of other medicines could transiently be reduced due to a decrease in gastrointestinal transit rate induced by PURGOLENE (see section 4.5).

Reactions related to the gastrointestinal tract occur most commonly. These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an increase in motility due to the pharmacologic effects of PURGOLENE (see section 4.8). Diarrhoea usually responds to dose reduction.

PURGOLENE contains 8,125 mmol sodium per dose, equivalent to 9,3 % of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 28 % of the WHO recommended maximum daily intake for sodium. PURGOLENE is considered high in sodium. This should be particularly taken into account for those on a low salt diet.

4.5 Interaction with other medicinal products and other forms of interaction

Macrogol (PEG) 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 transiently reduced during use with PURGOLENE (see section 4.4). There have been reports of decreased efficacy with some concomitantly administered medicines, e.g. anti-epileptics.

4.6 Fertility, pregnancy and lactation

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 (PEG), as in PURGOLENE, is negligible.

PURGOLENE can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to macrogol (PEG), as in PURGOLENE, is negligible.

PURGOLENE can be used during breastfeeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

a) Summary of the safety profile

Reactions related to the gastrointestinal tract occur most commonly. These reactions may occur as a consequence of expansion of the contents of the gastrointestinal tract, and an

increase in motility due to the pharmacologic effects of PURGOLENE. Mild diarrhoea usually responds to dose reduction.

b) Tabulated summary of adverse reactions

system organ Class	**Frequency**	**Side effects**
Immune system disorders	Frequency unknown	Allergic reactions (anaphylactic reactions, dyspnoea and skin reactions)
Metabolism and nutrition disorders	Frequency unknown	Electrolyte disturbances (hyperkalaemia, hypokalaemia)
Nervous system disorders	Frequency unknown	Headache
Gastrointestinal disorders	Frequency unknown	Abdominal pain, abdominal cramps, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anorectal discomfort
Skin and subcutaneous tissue disorders	Frequency unknown	Allergic skin reactions (angioedema, urticaria, pruritus, rash, erythema)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care

providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Macrogols are long linear polymers, also known as polyethylene glycols.

Mechanism of action

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.

The physiological consequence is an improved propulsive colonic transportation of the softened stools and a facilitation of defaecation.

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.

Pharmacological classification

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

Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06AD15

5.2 Pharmacokinetic properties

Absorption

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract.

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

Elimination

Any macrogol (PEG) that is absorbed is excreted via the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium (E950)

Lemon flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

48 months

6.4 Special precautions for storage

Sachet: Store at or below 25 ºC.

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

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

PURGOLENE is packed in cartons containing 5; 8; 10 or 20 aluminium foil sachets coated with low density polyethylene.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

42/11.5/0412

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/06/2016

10. DATE OF REVISION OF THE TEXT

15/12/2022