1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

PEGICOL PLAIN 6,9 g powder for reconstitution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of 6,9 g of PEGICOL PLAIN powder contains:

Macrogol 3 350	6,563 g
Potassium chloride	25,1 mg
Sodium bicarbonate	89,3 mg
Sodium chloride	175,4 mg

The content of electrolyte ions per sachet when diluted to 62,5 ml of solution is as follows:

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

Sugar free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution

PEGICOL PLAIN is a white, free-flowing, crystalline powder. The reconstituted solution is clear and colourless.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

PEGICOL PLAIN is indicated for:

- the treatment of chronic constipation.

4.2. Posology and method of administration

Posology

Chronic constipation

The usual starting dose is 1 sachet daily for children aged 2 to 6 years and 2 sachets a day for children aged 7 to 11 years. The dose should be adjusted up or down as required to produce regular soft stools.

The maximum dose needed does not normally exceed 4 sachets a day.

Special populations

Patients with impaired cardiovascular function

There is no clinical data for this group of patients.

Patients with renal insufficiency

There is no clinical data for this group of patients.

Paediatric population

PEGICOL PLAIN is not recommended for children below two years of age.

Method of administration

For oral administration

Each sachet should be dissolved in approximately 62,5 ml (quarter of a glass) of water. The correct number of sachets may be reconstituted in advance and kept covered and refrigerated for up to 24 hours. For example, 4 sachets can be made up into 250 ml of water.

4.3. Contraindications

PEGICOL PLAIN is contraindicated in:

- Patients with hypersensitivity to macrogol (PEG), sodium bicarbonate, sodium chloride, potassium chloride or to any of the excipients in PEGICOL PLAIN (see section 6.1).
- Patients with 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.
- PEGICOL PLAIN is not recommended for children below two years of age.

4.4 Special warnings and precautions for use

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.

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.

4.5 Interaction with other medicines and other forms of interaction

PEGICOL PLAIN raises the solubility of medicines that are soluble in alcohol and relatively insoluble in water. Therefore, theoretically it is possible that the absorption of medicines could be transiently altered. There have been isolated reports of decreased efficacy with some concomitantly administered medicines, e.g. anti-epileptics.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited amount of data from the use of PEGICOL PLAIN in pregnant women. Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 (PEG), as in PEGICOL PLAIN, is negligible.

Lactation

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

Fertility

There are no data on the effects of PEGICOL PLAIN on fertility in humans. There were no effects on fertility in studies in male and female rats.

4.7 Effects on ability to drive and use machines

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

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that PEGICOL PLAIN do not adversely affect their ability to do so safely (see section 4.8).

4.8 Undesirable effects

(a) Description of selected adverse reactions

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 PEGICOL PLAIN. Mild diarrhoea usually responds to dose reduction.

(b) Tabulated list of adverse reactions

System organ class	**Frequency unknown**
Immune system disorders	Allergic reactions (anaphylactic reactions, dyspnoea and skin reactions)
Metabolism and nutrition disorders	Electrolyte disturbances (hyperkalaemia, hypokalaemia)
Nervous system disorders	Headache
Gastrointestinal disorders	Abdominal pain, abdominal cramps, diarrhoea, vomiting, nausea, dyspepsia, abdominal distension, borborygmi, flatulence, anorectal discomfort

Skin and subcutaneous tissue disorders	Allergic skin reactions (angioedema, urticaria, pruritus, rash, erythema)
General disorders and administrative site conditions	Peripheral oedema

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. Healthcare providers are asked to report any suspected adverse reactions 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

4.9 Overdose

Symptoms

In the case of gross accidental overdosage, extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances. Severe pain or distension, associated with overdosage

Treatment

Can be treated by nasogastric aspiration.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 11.5 Medicines acting on the gastrointestinal tract.

Laxatives.Pharmacotherapeutic group: Osmotically acting laxatives

ATC code: A06AD15

Mechanism of action

PEGICOL PLAIN, an iso-osmotic laxative, is a combination of macrogol and electrolytes.

Macrogol (PEG) acts by virtue of its osmotic action in the gut, which induces a laxative effect. Macrogol (PEG) 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 (PEG) 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.

5.2. Pharmacokinetic properties

Absorption

Macrogol is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol that is absorbed is excreted via the urine. The laxative action of macrogol 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

None

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

Each carton contains 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Sachets are white laminates sealed in pairs. A perforation line allows for separation of the 2 sachets.

Not all packs and pack sizes are necessarily marketed.

6.6 Special precautions for disposal

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8 REGISTRATION NUMBER

A39/11.5/0385

9 DATE OF FIRST AUTHORISATION

11 August 2006

10 DATE OF REVISION OF TEXT

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