APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

PHOLIPEG HS 6,86 g sachet, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 6,86 g sachet of PHOLIPEG HS contains the following active substances:

Macrogol 3350	6,563 g
Sodium chloride	0,1754 g
Sodium bicarbonate	0,0893 g
Potassium chloride	0,0251 g

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

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

Contains artificial sweetener acesulfame potassium

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution.

A white crystalline powder in single-dose sachets with lemon odour.

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4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

PHOLIPEG HS is not recommended for children below two years of age.

Method of 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. [2]

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients of PHOLIPEG HS listed in 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

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intestinal tract such as Crohn's disease, ulcerative colitis and toxic megacolon.

4.4 Special warnings and precautions for use

PHOLIPEG HS should not be used in the presence of abdominal pain, nausea or vomiting. PHOLIPEG HS should not be used continuously unless directed by a medical practitioner. 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) PHOLIPEG HS 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 two weeks, a medical practitioner should be consulted.

Rectal bleeding or failure to have a bowel movement after use of PHOLIPEG HS may indicate a serious condition. PHOLIPEG HS use should be discontinued, and medical advice obtained.

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

The absorption of other medicines could transiently be reduced due to an increase in gastro-intestinal transit rate induced by PHOLIPEG HS (see section 4.5).

PHOLIPEG HS contains 93,4 mg (4,062 mmol) sodium (main component of cooking/table salt) per sachet. This is equivalent to 4,6 % of the recommended maximum daily dietary intake of sodium for an adult.

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4.5 Interaction with other medicines and other forms of interaction

Medicinal products in solid dose form taken within one hour of administration of large volumes of macrogol preparations (as used when treating faecal impaction) may be flushed from the gastrointestinal tract and not absorbed.

Macrogol raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water.

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with PHOLIPEG HS (see section 4.4). There have been reports of decreased efficacy with some concomitantly administered medicinal products, e.g., anti-epileptics.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is limited amount of data from the use of PHOLIPEG HS in pregnant women. Studies in animals have shown indirect reproductive toxicity (see section 5.3). PHOLIPEG HS can be used during pregnancy.

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to Macrogol 3350 is negligible. PHOLIPEG HS can be used during breast-feeding.

Fertility

There are no data on the effects of PHOLIPEG HS on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

4.7 Effects on ability to drive and use machines

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

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4.8 Undesirable effects

a. Summary of the safety profile

Reactions related to the gastrointestinal tract occur most frequently. 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 PHOLIPEG HS. Vomiting may be resolved if the dose is reduced or delayed.

b. Tabulated summary of adverse reactions

The adverse reactions are listed below according to system organ class and frequency.

MedDRA system organ class	**Frequency**	**Adverse reactions**
Immune system disorders	Less frequent	Allergic reactions, including anaphylactic reactions
	Frequency unknown	Dyspnoea and skin reactions (see below)
Skin and subcutaneous tissue disorders	Frequency unknown	Allergic skin reactions including angioedema, urticaria, pruritus, rash, erythema
Metabolism and nutrition disorders	Frequency unknown	Electrolyte disturbances, particularly hyperkalaemia and hypokalaemia
Nervous system disorders	Frequency unknown	Headache
Gastrointestinal disorders	Frequent	Abdominal pain, borborygmi, diarrhoea, vomiting, nausea and anorectal discomfort
	Less frequent	Abdominal distension, flatulence

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MedDRA system organ class	Frequency	Adverse reactions
	Frequency unknown	Dyspepsia and peri-anal inflammation
General disorders and administration site conditions	Frequency unknown	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. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Medicine Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Severe abdominal pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Osmotically acting laxatives. ATC code: A06A D65

Pharmacological classification: A11.5 Medicines acting on the gastrointestinal tract. Laxatives.

5.1 Pharmacodynamic properties

PHOLIPEG HS, 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

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faecal water without net gain or loss of sodium, potassium and water.

5.2 Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastrointestinal tract. Any macrogol 3350 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acesulfame potassium

Lemon flavour*

*(Lemon flavour contains the following constituents: acacia gum, flavouring preparation and nature identical flavouring substance).

6.2 Incompatibilities

None are known.

6.3 Shelf life

48 months.

Reconstituted solution: 24 hours.

6.4 Special precautions for storage

Sachet: Store at or below 25 °C.

Reconstituted solution: Store at 2 – 8 °C (in a refrigerator and covered).

6.5 Nature and contents of container

PHOLIPEG HS 6,86 g powder for oral solution is packed in polythene laminated aluminium

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sachets.

Sachets are packed in printed carton made of white board & proposed pack sizes are boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused solution should be discarded within 24 hours.

7 HOLDER OF CERTIFICATE OF REGISTRATION

STRIDES PHARMA (PTY) LTD

106 16th Road

Building 2

Midrand

South Africa

1685

8 REGISTRATION NUMBERS

PHOLIPEG HS: 53/11.5/0675

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 February 2023

10 DATE OF REVISION OF THE TEXT

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