SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Laxogol powder for oral solution, sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following quantitative composition of active ingredients:

Macrogol 3350	13.125 g
Sodium Chloride	0.3507 g
Sodium Hydrogen Carbonate	0.1785 g
Potassium Chloride	0.0466 g

The content of electrolyte ions per sachet following reconstitution in 125 ml of water is equivalent to:

Sodium	65 mmol/l
Chloride	53 mmol/l
Hydrogen Carbonate (Bicarbonate)	17 mmol/l
Potassium	5 mmol/l

Excipient with known effect: Contains sorbitol (E420).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution

Single-dose sachet containing a free flowing white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of chronic constipation.

4.2 Posology and method of administration

Laxogol is for oral use.

A course of treatment for chronic constipation with Macroherm does not normally exceed 2 weeks, although this can be repeated if required. As for all laxatives, prolonged use is not usually recommended.

Adults, adolescents and the elderly: 1-3 sachets daily in divided doses, according to individual response.

Children below 12 years old: Not recommended.

Patients with renal insufficiency: No dosage change is necessary.

Administration:
Each sachet should be dissolved in 125 ml water.

4.3 Contraindications

Laxogol is contraindicated in intestinal obstruction or perforation caused by functional or structural disorder of the gut wall, ileus and in patients with severe inflammatory conditions of the intestinal tract (e.g. ulcerative colitis, Crohn's disease and toxic megacolon).
Hypersensitivity to the active substances or any of the excipients.

4.4 Special warnings and precautions for use

Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluids/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) Macrogol Hermes should be stopped immediately and electrolytes measured and any abnormality should be treated appropriately.

The lemon lime flavour in MacrogolHermes contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Macrogol 3350 raises the solubility of medicinal products that are soluble in alcohol and relatively insoluble in water. It is a theoretical possibility that absorption of these drugs could be reduced transiently.

There have been isolated reports of decreased efficacy with some concomitantly administered medicinal products, e.g. anti-epileptics.

4.6 Pregnancy and lactation

There is no experience with the use of Laxogol during pregnancy and lactation and it should only be used if considered essential by the physician.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Reactions related to the gastrointestinal tract are the most common to occur.

Immune System Disorders:
Allergic reactions, including anaphylactic reaction. Other symptoms of allergic reactions include dyspnoea, urticaria and pruritus.

Gastro-intestinal Disorders:
Potential gastro-intestinal effects that may occur include abdominal distension and pain, anal discomfort, flatulence, vomiting, borborygmi and nausea.
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 Laxogol.
Mild diarrhoea may also occur, but normally resolves after dose reduction.

4.9 Overdose

Severe distension or pain can be treated using nasogastric aspiration. Vomiting or diarrhoea may induce extensive fluid loss, possibly leading to electrolyte disturbances that should be treated appropriately.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Macrogol 3350 induces a laxative effect through its osmotic action in the gut. It 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 the 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.

Clinical studies using the listed active substances for the treatment of chronic constipation have shown that the dose required to produce normally formed stools tends to decrease over time. Many patients, respond to between one and two sachets a day, but this dose should be adjusted depending on individual response.

5.2 Pharmacokinetic properties

Macrogol 3350 is virtually unabsorbed from the gastro-intestinal tract and is excreted, unaltered, in faeces. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3 Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, although no tests of its effects on reproduction or genotoxicity have been conducted.

There are no long-term animal toxicity or carcinogenicity studies involving macrogol 3350, although there are toxicity studies using high levels of orally administered high-molecular weight macrogols that provide evidence of safety at the recommended therapeutic dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Saccharin sodium
Orange flavour
(Orange flavour contains: flavouring substances and flavouring preparations, maltodextrin, acacia gum, alpha-tocopherol)
Lemon lime flavour
(Lemon lime flavour contains: flavouring preparations, maltodextrin, mannitol, gluconolactone, sorbitol (E420), acacia gum, colloidal anhydrous silica)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

Reconstituted solution: 24 hours

6.4 Special precautions for storage

Sachet: Do not store above 25 °C.
Reconstituted solution: Store covered in a refrigerator (2 °C to 8 °C).

6.5 Nature and contents of container

The sachet is composed of paper, ethylene / methacrylic acid co-polymer and aluminium.

Sachets are packed in cartons of 2, 6, 8, 10, 20, 30, 50, 60 (2x30) and 100 (2x50).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

After 24 hours, any unused solution should be discarded.

7 MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8 MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10 DATE OF REVISION OF THE TEXT

2015-11-24