SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Omnilax 4 g powder for oral solution in sachet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 4 g of macrogol 4000.

Excipients with known effect:
Each sachet contains 0.28 mg sorbitol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution in sachet.

Off white powder with a scent and taste of orange-grapefruit.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of constipation in children from 6 months to 8 years.

An organic disorder should have been ruled out by a physician, especially in the age group under 2 years, before initiation of treatment. Omnilax 4 g should remain temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3 month treatment course. If symptoms persist despite associated dietary measures, an underlying cause should be suspected and treated.

4.2 Posology and method of administration

Oral use.

Posology
From 6 months to 1 year: 1 sachet (4 g) per day.
From 1 to 4 years: 1-2 sachets (4-8 g) per day.
From 4 to 8 years: 2-4 sachets (8-16 g) per day.
The daily dose should be adjusted according to the clinical response.

The effect of Omnilax becomes apparent within 24-48 hours after its administration.

Paediatric population
In children, treatment should not exceed 3 months due to lack of clinical data for treatment lasting longer than 3 months. Treatment-induced restoration of bowel movements should be maintained by appropriate lifestyle and dietary measures.

Treatment should be stopped gradually and resumed if constipation recurs.

Method of administration
The content of the sachet should be dissolved in approximately 50 ml water and be taken in the morning if the dose is one sachet per day or be taken in the morning and the evening if the dose is more than one sachet per day.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1,
- Severe inflammatory bowel disease (ulcerative colitis, Crohn's disease) or toxic megacolon associated with symptomatic stenosis.
- Gastrointestinal perforation or risk of gastrointestinal perforation
- Ileus or suspected intestinal blockage or symptomatic stenosis
- Abdominal pain without known cause.

4.4 Special warnings and precautions for use

Efficacy data on children below 2 years of age are limited.

The treatment of constipation with any medicinal product is only an adjuvant to a healthy lifestyle and diet, for example:
- increased intake of fluids and dietary fibres,
- appropriate physical activity and rehabilitation of the bowel reflex.

An organic disorder should have been ruled out before initiation of treatment.

After 3 months of treatment, a complete clinical assessment regarding the constipation should be performed.

This medicinal product contains macrogol (polyethylene glycol). Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema) to medicinal products containing macrogol (polyethylene glycol) has been reported, see section 4.8.

Omnilax contains sorbitol. Patients with the following rare hereditary conditions should not take this medicinal product: fructose intolerance.

In case of diarrhoea, caution should be exercised in patients prone for disturbances of water-electrolyte balance (e.g. elderly, patients with impaired hepatic or renal function or patients taking diuretics) and electrolyte control should be considered.

Use with caution in patients with impaired gag reflex and patients prone to regurgitation or aspiration. Cases of aspiration have been reported when large volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. Neurologically impaired children with oromotor dysfunction are particularly at risk of aspiration.

In patients with swallowing problems, who need the addition of a thickener to solutions to enhance an appropriate intake, interactions should be considered, see section 4.5.

<u>Precaution for use</u>
Omnilax 4 g does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic children or children on a galactose-free diet.

4.5 Interaction with other medicinal products and other forms of interaction

There is a possibility that the absorption of other medicinal products could be transiently reduced during use with Omnilax, particularly medicinal products with a narrow therapeutic index or short half-life such as digoxin, anti-epileptics, coumarins and immunosuppressive agents, leading to decreased efficacy.
Omnilax may result in a potential interactive effect if used with starch-based food thickeners. The macrogol ingredient counteracts the thickening effect of starch, effectively liquefying preparations that need to remain thick for people with swallowing problems.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity, see section 5.3.

There is limited amount of data (less than 300 pregnancies) from use of macrogol 4000 in pregnant women. No adverse effects during pregnancy are anticipated, since systemic exposure to Omnilax is negligible. Omnilax can be used during pregnancy.

Breastfeeding
There are no data on the excretion of Omnilax in breast milk. No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of breast-feeding women to macrogol 4000 is negligible. Omnilax can be used during breast-feeding.

Fertility
No fertility studies were conducted with Omnilax, however since macrogol 4000 is not significantly absorbed, no effect on fertility is anticipated.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and/or use machines have been performed.

4.8 Undesirable effects

The undesirable effects listed in the table below have been reported during clinical trials (including 147 children aged from 6 months to 15 years) and post-marketing use. Generally, adverse reactions have been mostly mild and transitory and have mainly concerned the gastrointestinal system.

Adverse drug reactions are listed under headings of frequency using the following categories:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); unknown (cannot be estimated from the available data).

System Organ Class	**Adverse reactions**
Gastrointestinal disorders	
Common	Abdominal pain Diarrhoea*
Uncommon	Vomiting Abdominal distension Nausea
Immune system disorders	
Unknown	Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus)

* Diarrhoea may cause perianal soreness

Adult population
In adults, the following additional undesirable effects have been observed in clinical trials or post-marketing:
Gastro-intestinal disorders:
Uncommon: Defaecation urgency, faecal incontinence

Metabolism and Nutrition Disorders
Unknown: Electrolytes disorders (Hyponatremia, Hypokalaemia) and or dehydration, especially in elderly patients

Immune system disorders:
Unknown: Erythema

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Diarrhoea, abdominal pain and vomiting have been reported. In cases of severe diarrhoea, weight loss and electrolytes imbalance may occur. Diarrhoea due to excessive dosing disappears when treatment is temporarily interrupted or the dosage is reduced.

Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for constipation. Osmotically acting laxatives.
ATC code: A06AD15

High molecular weight (4000) macrogols are long, linear polymers which retain water molecules by means of hydrogen bonds. When administered by the oral route, they lead to an increase in volume of intestinal fluids. The volume of unabsorbed intestinal fluid accounts for the laxative properties of the solution.

5.2 Pharmacokinetic properties

The pharmacokinetic data confirm that macrogol 4000 undergoes neither gastrointestinal resorption nor biotransformation following oral ingestion.

5.3 Preclinical safety data

Toxicological studies in different species of animals did not reveal any signs of systemic or gastrointestinal toxicity of macrogol 4000. Macrogol 4000 had no teratogenic or mutagenic effect. Potential drug interactions studies performed in rats on some NSAIDs, anticoagulants, gastric anti-secretory agents, or on a hypoglycaemic sulfamide showed that macrogol 4000 did not interfere with gastrointestinal absorption of these compounds. No carcinogenicity studies have been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium (E954)
Flavour (orange-grapefruit) containing:
maltodextrin, sorbitol (E420), butylhydroxyanisole (E320), acacia (E414).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 year

Reconstituted solution should be stored well covered in a refrigerator (2°C-8°C) and is stable for 6 hours.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Sachet (PE/aluminium/PE/paper).
Pack sizes: 10, 20, 30 or 50 sachets per package.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal <and other handling>

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Pro Health Pharma Sweden AB
Genetor,
Kungstorget 8,
252 78 Helsingborg, Sweden

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD month YYYY}
Date of latest renewal: {DD month YYYY}

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

2024-09-19