

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Omnilax 10 g powder for oral solution, in sachet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One sachet contains 10 g of macrogol 4000.

Excipients with known effect:

One sachet contains 0.7 mg sorbitol and 0.007 mg.

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 adults and children aged 8 years and above.

An organic disorder should have been ruled out before initiation of treatment. Omnilax should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-month treatment course in children. 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

1-2 sachets (10-20 g) per day, preferably taken as a single dose in the morning. The daily dose should be adjusted according to the clinical response and may range from one sachet every other day (especially in children) up to 2 sachets a day.

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 more than 3 months. Treatment-induced restoration of bowel movements will be maintained by lifestyle and dietary measures.

Method of administration

The content of each sachet should be dissolved in about 50 ml of water just before use and taken in the morning. The resultant solution will be clear and transparent like water.

4.3 Contraindications

- Severe inflammatory bowel disease (such as ulcerative colitis, Crohn's disease) or toxic megacolon
- Digestive perforation or risk of digestive perforation
- Ileus or suspicion of intestinal obstruction or symptomatic stenosis
- Painful abdominal syndromes of indeterminate cause.
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1,

4.4 Special warnings and precautions for use

Special warning

The treatment of constipation with any medicinal product is only an adjuvant to a healthy lifestyle and diet, for example:

- increased intake of liquids and dietary fibre,
- advice on appropriate physical activity and rehabilitation of the bowel reflex.

An organic disorder should have been excluded before initiation of treatment.

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

This medicine contains 0.7 mg of sorbitol in each sachet. This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially "sodium-free".

In case of diarrhoea, caution should be exercised in patients at risk of disturbances of water-electrolyte balance (e.g. the elderly, or patients with impaired hepatic or renal function or patients taken 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 extensive volumes of polyethylene glycol and electrolytes were administered with nasogastric tube. Neurologically impaired children who have oral-motor 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.

Precautions for use

Omnilax does not contain a significant quantity of sugar or polyol and can be prescribed to diabetic patients or patients 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 are limited amount of data (less than 300 pregnancy outcomes) for the use of Omnilax 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 the breast-feeding woman 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

Adverse drug reactions are listed under headings of frequency using the following categories:

Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from the available data).

Adult population

The undesirable effects listed in the table below have been reported during clinical trials (including 600 adult patients) and post-marketing use. Generally, adverse reactions have been mostly mild and transitory and have mainly concerned the gastrointestinal system.

System Organ Class	Adverse reactions
<u>Gastrointestinal disorders</u>	
<i>Common</i>	Abdominal pain Abdominal distension Diarrhoea* Nausea
<i>Uncommon</i>	Vomiting Defaecation urgency Fecal incontinence
<u>Metabolism and nutrition disorders</u>	
<i>Not known</i>	Electrolytes disorders (hyponatremia, hypokalaemia) and/or dehydration, especially in elderly patients
<u>Immune system disorders</u>	
<i>Not known</i>	Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema)

Paediatric population

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. As in adult population, adverse reactions have generally been mostly mild and transitory and have mainly concerned the gastrointestinal system.

System Organ Class	Adverse reactions
<u>Gastrointestinal disorders</u>	
<i>Common</i>	Abdominal pain Diarrhoea*
<i>Uncommon</i>	Vomiting Abdominal distension Nausea
<u>Immune system disorders</u>	
<i>Not known</i>	Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus)

* Diarrhoea may cause perianal soreness

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.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 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 the 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 local 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 antisecretory agents, or on a hypoglycaemic sulfamide showed that Omnilax 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), gum arabic (E414).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

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

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

6.5 Nature and contents of container

Sachet (paper, aluminium and PE).

Pack sizes: 10, 20, 30, 50 or 100 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

[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

[To be completed nationally]

2025-11-11