SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Omnilax 10 g powder for oral solution, 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 sulphur dioxide.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution, sachet.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Functional constipation in adults and children aged 8 years and above.

An organic disorder should have been ruled out before initiation of treatment. Omnilax should be a temporary adjuvant treatment to lifestyle and dietary management appropriate for constipation, with a maximum 3-month treatment duration in children. If symptoms persist despite dietary changes, 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. Each sachet should be dissolved in a glass of water. 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 treatment lasting longer than 3 months. Treatment-induced restoration of bowel movements should be maintained by appropriate lifestyle and dietary measures.

Omnilax is not approved for treatment of children below 8 years of age.

**Method of administration**
The content of the sachet should be dissolved in a glass of water.
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
- 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

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.

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 very small amounts of sulphur dioxide (0.007 mg per sachet). Sulphur dioxide may rarely cause serious hypersensitivity reactions and bronchospasm.

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.

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.

Paediatric population

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

4.5 Interaction with other medicinal products and other forms of interaction

Macrogol 4000 might modify the intestinal absorption of other medicinal products administered concomitantly.

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 effects during pregnancy are anticipated, since systemic exposure to Omnilax is negligible. Omnilax can be used during pregnancy.
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.

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**

Omnilax has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

Adverse reactions are listed according to the following frequencies:
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); not known (cannot be estimated from the available data).

**Adult population**
The undesirable effects listed in the table below have been reported for macrogol 4000 in clinical trials (including 600 adult patients) and during post-marketing use. Generally, adverse reactions have been mild and transitory and have mainly concerned the gastrointestinal system.

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Abdominal pain</td>
</tr>
<tr>
<td><strong>Common</strong></td>
<td>Vomiting</td>
</tr>
<tr>
<td><strong>Uncommon</strong></td>
<td>Electrolytes disorders (hyponatremia, hypokalaemia) and/or dehydration, especially in elderly patients</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Not known</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus, erythema)</td>
</tr>
</tbody>
</table>

**Paediatric population**
The undesirable effects listed in the table below have been reported for macrogol 4000 in clinical trials (including 147 children aged from 6 months to 15 years) and during post-marketing use. As in the adult population, adverse reactions have generally been mild and transitory and have mainly concerned the gastrointestinal system.

<table>
<thead>
<tr>
<th>System Organ Class</th>
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</tr>
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<tbody>
<tr>
<td>Gastrointestinal disorders</td>
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<td>System Organ Class</td>
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</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>Nausea</td>
</tr>
<tr>
<td>Not known</td>
<td>Hypersensitivity (anaphylactic shock, angioedema, urticaria, rash, pruritus)</td>
</tr>
</tbody>
</table>

* 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. Excessive dosing can cause diarrhoea which generally disappears when treatment is temporarily interrupted or the dose is reduced.

Excessive fluid loss due to 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 to which water molecules bind by means of hydrogen bonds. After oral administration, the volume of intestinal fluids increases. The volume of unabsorbed intestinal fluid accounts for the laxative properties of the macrogol solution.

**5.2 Pharmacokinetic properties**

Pharmacokinetic data confirms that no intestinal absorption or biotransformation of macrogol occur following oral administration.

**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 did not show any teratogenic or mutagenic effect. Studies concerning potential drug interactions 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) 0.7 mg, sulphur dioxide (E220) 0.007 mg, gum arabic (E414) 1.61 mg.

**6.2 Incompatibilities**
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 (PE/aluminium/PE/paper).
Pack sizes: 2, 4, 6, 8, 10, 12, 14, 20, 22, 24, 30, 50, 60, 100, 200 or 250 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
Kullagatan 8-10
252 20 Helsingborg
Sweden
Telephone: +46 721 903655
info@prohealthpharma.se

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

19 February 2018

[To be completed nationally]
Detailed information on this medicinal product is available on the website of {name of MS Agency (link)}