Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Peglax 10 g powder for oral solution in sachet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 10 g of macrogol 4000.
Excipient(s) with known effect: 0.0000018 mg of sulphur dioxide (E-220) per sachet and less than 1 mmol of sodium per sachet.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Powder for oral solution in sachet.
Almost white powder

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. Peglax should remain a temporary adjuvant treatment to appropriate lifestyle and dietary management of constipation, with a maximum 3-months 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 to 2 sachets per day, preferably taken as a single dose in the morning. It is recommended to drink 125 ml of liquids (e.g. water) after each dose.

The effect of Peglax becomes apparent within 24 to 48 hours after its administration.
The daily dose should be adapted according to the clinical effects and may range from one sachet every other day (especially in children) up to 2 sachets a day.

Treatment should be stopped gradually and resumed if constipation recurs.

Paedriatic population
1 to 2 sachets per day, preferably taken as a single dose in the morning. It is recommended to drink 125 ml of liquids (e.g. water) after each dose.

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

Method of administration
Each sachet should be dissolved in a glass of water (125 ml approximately) just before use. The resultant solution will be clear and transparent like water.

4.3 Contraindications

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

- Painful abdominal syndromes of indeterminate 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 liquids and dietary fibre,
- Appropriate physical activity and rehabilitation of the bowel reflex.
Due to the presence of sulphur dioxide, Peglax may rarely cause severe hypersensitivity reactions and bronchospasm.
In case of diarrhoea, caution should be exercised in patients who are prone to a disturbance of water and/or electrolyte balance (e.g. the 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 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.

Avoid mixing PEG laxatives and starch-based thickeners in patients with dysphagia, considered 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.

Hypersensitivity reactions (rash, urticaria, and oedema) have been reported with drugs containing macrogol (polyethylene glycol). Exceptional cases of anaphylactic shock have been reported.

Peglax contains a non-significant amount of sugar or polyol and thus may be prescribed to diabetic patients or patients on a galactose-free diet.

This medicine contains less than 1 mmol sodium (23 mg) per sachet that is to say essentially "sodium- free".

According to the way of action of macrogol, it is recommended to intake liquids during the treatment with this medicine (please see section 5.1).

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

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 Casenlax. The therapeutic effect of medicinal products with a narrow therapeutic index may be particularly affected (e.g antiepileptics, digoxin and immunosuppressive agents).

Peglax 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 Peglax in pregnant women.
No effects during pregnancy are anticipated, since systemic exposure to Peglax is negligible. Peglax can be used during pregnancy.

Lactation
There are no data on the excretion of Peglax 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. Peglax can be used during breast feeding.

Fertility:
No fertility studies were conducted with Peglax however since macrogol 4000 is not significantly absorbed no effects are anticipated.

4.7 Effects on ability to drive and use machines

Peglax has no influence on ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects 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); 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 minor and transitory and have mainly concerned the gastrointestinal system:

System Organ Class	Adverse reactions
Immune system disorders	
Very rare	Hypersensitivity reactions (Pruritus, Rash, Face oedema, Quincke oedema, Urticaria, Anaphylactic shock)
Not known	Erythema
Metabolism and Nutrition Disorders	
Not known	Electrolytes disorders (Hyponatremia, Hypokalaemia) and/or dehydration, especially in elderly patients
Gastrointestinal disorders	
Common	Abdominal pain and/ or distension Diarrhoea Nausea
Uncommon	Vomiting Urgency to defecate Fecal incontinence

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 minor and transitory and have mainly concerned the gastrointestinal system:

System Organ Class	Adverse reactions
Immune system disorders	
Not known	Hypersensitivity reactions (Anaphylactic shock, Angioedema, Urticaria, Rash, Pruritus)
Gastrointestinal disorders	
Common	Abdominal pain Diarrhoea*
Uncommon	Vomiting Bloating Nausea

* 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 HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

Overdose could lead to diarrhea, abdominal pain and vomiting which disappears when treatment is temporarily interrupted or the dosage is reduced.
Excessive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

Cases of aspiration have been reported when extensive volumes of macrogol (polyethylene glycol) and electrolytes were administered with nasogastric tube. Neurologically impaired children who have oromotor dysfunction are particularly at risk of aspiration.

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. This is why an adequate hydration is important during the treatment.
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 conducted in different animal species did not reveal any sign of systemic or local gastrointestinal toxicity.Macrogol 4000 had no teratogenic or mutagenic effect.

No carcinogenicity studies have been performed.

Macrogol 4000 was not teratogenic in rats or rabbits.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium (E 954)
Apple flavour (flavourings identical to natural substances, natural flavours, flavouring preparations, maltodextrine, gum arabic (E 414), sulphur dioxide (E 220), alpha tocopherol (E 307))

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Sachet made of heat-sealable polyethylene, aluminium and polyester film (polyester/aluminium/polyethylene complex). Single dose sachets presented in pack sizes of 8, 10, 20, 30, 50, 60 and 100 sachets.
Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Casen-Recordati S.L.
Autovia De Logrono, km. 13,300
50180 Utebo (Zaragoza)
Spain

8 MARKETING AUTHORISATION NUMBER

PA2028/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th June 2013
Date of last renewal: 17th January 2016

10 DATE OF REVISION OF THE TEXT

March 2026