**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**PEGLAX 10g Powder for oral solution in sachet**

**Macrogol 4000**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**:



## 1. WHAT PEGLAX IS AND WHAT IT IS USED FOR

The name of this medicine is Peglax 10g powder for oral solution in sachet.

Peglax is considered as osmotic laxative.

Peglax is used for the symptomatic treatment of constipation in adults and children 8 years old and over. It should be used with appropriate changes to lifestyle and diet (see section 2).

You must talk to a doctor if you do not feel better or if you feel worse.

This medicine contains Macrogol (P.E.G. = polyethylene glycol).
In the case of constipation, the maximum treatment period in children is 3 months.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PEGLAX

**Occasional constipation:**

Occasional constipation may be related to a recent change in your lifestyle. There are medicines that can be used for short term treatment. Ask the opinion of your doctor in the case of recent constipation which cannot be explained by changes in your lifestyle, or in the case of constipation associated with pain, fever or abdominal swelling.

**Chronic constipation (long term constipation):**

Chronic constipation may be caused by:

- Intestinal disease that requires a physician's advice.
- Intestinal dysfunction (imbalance) due to dietary habits and lifestyle.

The treatment includes among others:

- An increase in the proportion of fibre in the diet (vegetables, wholegrain bread and fruit);
- Increase water and fruit juice intake;
- Increase physical activity (sports, walking ...)
- Rehabilitation of the defecation reflex.

**Do not take Peglax**

- If you are allergic to Macrogol (P.E.G. = polyethylene glycol) or any of the other ingredients of this medicine (listed in section 6).
- If you have any intestine or colon disease (such as ulcerative colitis, Crohn's disease).
- If you have abdominal pain of undetermined cause.
- If you have or suspect a gastrointestinal perforation.
- If you have or suspect a bowel obstruction.
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**Warnings and Precautions**

Talk to your doctor, pharmacist <or nurse> before taking Peglax.

If you develop diarrhoes following treatment with Peglax you may be at risk of developing electrolyte disorders (a decrease in certain salts in the blood). You are more likely to be at risk if you are an older person, or have liver or kidney problems, or are taking diuretics (water tablets). If you are one of these people and you develop diarrhoea you should see your doctor to have your electrolyte levels checked with a blood test.

Avoid mixing Peglax and starch-based food thickeners if you have difficulties with swallowing. This may result in a watery liquid which could get into your lungs and cause pneumoniae if you cannot swallow properly.

If you need to thicken fluids in order to swallow them safely, Peglax may counteract the effect of the thickener.

**Children**

Ask your doctor´s opinion before administering this treatment to your child, in order to exclude any organic cause of constipation. After 3 months of treatment, your doctor should evaluate your child clinical condition.

**Other medicines and Peglax.**

Peglax may delay the absorption of other medicines, making them less effective or ineffective especially those with a narrow therapeutic index (e.g antiepileptics, digoxin and immunosuppressive agents). Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

**Pregnancy**

Peglax can be used during pregnancy.

**Breast-feeding**

Peglax can be used during breast-feeding.

**Driving and using machines**

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

**Peglax contains sulphur dioxide**.

This medicine may rarely cause severe hypersensitivity reactions and bronchospasm (difficulty breathing) because of its sulphur dioxide content.

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

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.

## 3. HOW TO TAKE PEGLAX

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For oral use.
The recommended dose is: 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 daily dose should be adjusted according to the clinical effects obtained and may range from one sachet every other day (especially in children) to up to a maximum of 2 sachets per day.

The effect of Peglax occurs within 24 to 48 hours after administering.

Dissolve the content of the sachet in a glass of water (at least 125 ml) immediately before use and drink the liquid.

Improvement in the frequency of your bowel movements after taking Peglax can be maintained by keeping to a healthy lifestyle and diet.

**Use in children and adolescents**

For children, the treatment must not exceed 3 months due to a lack of clinical data from more than 3 months treatments.

Treatment should be stopped gradually and resumed if constipation recurs.

**If you take more Peglax than you should**

You can develop diarrhoea, abdominal pain and vomiting which disappears when treatment is temporarily interrupted or the dose is reduced.

If you suffer from severe diarrhoea or vomiting you should contact a doctor as soon as possible as you may require treatment to prevent loss of salts (electrolytes) from fluid loss.

**If you forget to take Peglax**

Do not take a double dose to make up for a forgotten dose.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effects are considered to be the allergic (hypersensitivity) reactions that include pruritus (itchy rash), rash, face oedema (swelling of the face), quincke oedema (rapid swelling of the deep layers of the skin), urticaria (nettle rash) and anaphylactic shock. Its frequency has been reported as very rare (may affect up to 1 in 10,000 people) in adult population and as unknown (frequency cannot be estimated from available data) in paediatric population. If you notice any of the reactions listed above, please stop taking this medicine immediately and seek urgent medical advice.

**Adults:**

Generally, adverse reactions have been minor and transitory and have mainly concerned the gastrointestinal system. These side effects include:

**Common (may affect up to 1 in 10 people)**

- Abdominal pain
- Abdominal distension
- Diarrhoea
- Nausea

**Uncommon (may affect up to 1 in 100 people)**

- Vomiting
- Urgency to defecate
- Faecal incontinence

**Not known (frequency cannot be estimated from available data)**

- Electrolyte disorders (low blood levels of sodium and potassium: hyponatremia, hypokalemia)
- Dehydration, caused by severe diarrhoea especially in elderly patients
- Erythema

**Children/adolescents:**

As in adult population, adverse reactions have generally been minor and transitory and have mainly concerned the gastrointestinal system. These side effects include:

**Common (may affect up to 1 in 10 people)**

- Abdominal pain
- Diarrhoea (may cause perianal soreness)

**Uncommon (may affect up to 1 in 100 people)**

- Vomiting
- Bloating
- Nausea

Excessive doses can cause diarrhoea, abdominal pain and vomiting which disappears generally when the dose is reduced or treatment temporarily interrupted.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE PEGLAX

Keep this medicine out of the sight and reach of children.

This medicine does not require special storage conditions.

Do not use this medicines after the expiry date which is stated on the sachet/outer carton after EXP.

The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What Peglax contains**

The active substance is: Macrogol 4000
Each sachet contains 10g of macrogol 4000.

The other ingredients are: Saccharin sodium (E 954) and apple flavour (flavourings identical to natural substances, natural flavours, flavouring preparations, maltodextrine, gum arabic (E 414), sulphur dioxide (E 220), alpha tocopherol (E 307)). See section 2 “Peglax contains sulphur dioxide”

**What Peglax looks like and contents of the pack**

Peglax is an almost white powder in a sachet for making up a solution.

It is available in packs of 8, 10, 20, 30, 50, 60 or 100 sachets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Casen Recordati, S.L.
Autovía de Logroño, Km 13,300
50180 UTEBO. Zaragoza (Spain)

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**
Bulgaria: Касенлакс
Belgium, Luxembourg: Transilax
Cyprus, Lithuania: Macrogol 4000 Casen Recordati
Denmark, Finland, France, Italy, Norway, Portugal, Spain, Sweden: Casenlax
Estonia, Latvia, Romania: Proctolax
Germany: Laxbene 10
Greece: Cleenlax forte
Ireland, United Kingdom (Northern Ireland): Peglax

**This leaflet was last revised in March 2026**

**Other sources of information**

Detailed information on this medicine is available on the website of Irish Medicines Board
www.hpra.ie