

PACKAGE INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION TO THE USER

PEGLax 10g Powder for oral solution in sachet

Macrogol 4000.

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you .

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What PEGLAX is and what it is used for
2. What you need to know before you take PEGLAX
3. How to take PEGLAX
4. Possible side effects
5. How to store PEGLAX
6. Contents of the pack and other information

1. WHAT PEGLAX IS AND WHAT IT IS USED FOR

The name of this medicine is PEGLAX, 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 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 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

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before taking PEGLAX.

If you develop diarrhoea 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.

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 Casenlax.

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 PEG LAX

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

For oral use.

The usual dose is:

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 PEG LAX 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 Casenlax 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 the Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 medicine 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 (E954) and Apple flavour (Natural flavour, maltodextrine, gum arabic E414, sulphur dioxide E220, alpha tocopherol E307). See section 2 “Casenlax 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 authorized in the Member States of EEA under the following names:

Bulgaria: Касенлакс 10 g прах за перорален разтвор в саше

Belgium: Transilax 10 g

Cyprus: Macrogol 4000 Casen Recordati 10 g κόνις για πόσιμο διάλυμα σε φακελίσκο

Denmark: Casenlax 10g pulver til oral opløsning i brev

Estonia: Proctolax

Finland: Casenlax 10g jauhe oraaliliuosta varten, annospussi

France: Casenlax 10g poudre pour solution buvable

Germany: Laxbene 10 g Pulver zur Herstellung einer Lösung zum Einnehmen, in Beuteln, für Kinder ab 8 Jahren und Erwachsene

Greece: Cleenlax forte 10 g κόνις για πόσιμο διάλυμα σε φακελίσκο

Ireland: PEGLax 10g Powder for oral solution in sachet
Italy: Casenlax 10g polvere per soluzione orale in bustina
Latvia: Proctolax 10 g pulveris iekšķīgi lietojama šķīduma pagatavošanai paciņā
Lithuania: Macrogol 4000 Casen Recordati 10 g milteliai geriamajam tirpalui paketėlyje
Luxembourg: Transilax 10 g
Netherlands: Casenlax 10 g poeder voor drank
Norway: Casenlax 10g pulver til mikstur, oppløsning i dosepose
Portugal: Casenlax 10g pó para solução oral em saquetas
Romania: Proctolax 10g, pulbere pentru soluție orală, in plic
Spain: Casenlax 10g polvo para solución oral en sobre
Sweden: Casenlax 10g pulver till oral lösning i dospåse
United Kingdom (Northern Ireland): PEGLax 10g Powder for oral solution in sachet

This leaflet was last revised in: April 2025