

PACKAGE INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION TO THE USER

PEGLax 10g Powder for oral solution in sachet

Macrogol 4000.

Please read this entire leaflet carefully before you start taking this medicine.

This medicine is available without prescription. However, you should always take PEGLAX 10g carefully in order to obtain the best results.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What PEGLAX 10g is and what it is used for
2. What information is to be known before taking PEGLAX 10g
3. How to take PEGLAX 10g
4. What are the possible side effects
5. How to store PEGLAX 10g
6. Further information

1. WHAT PEGLAX 10g IS AND WHAT IT IS USED FOR

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

PEGLAX 10g is considered as osmotic laxative.

PEGLAX 10g is indicated for the symptomatic treatment of constipation in adults and children 8 years old and over and regarded as temporary adjunctive therapy in an appropriate lifestyle and in dietary measures.

In the case of constipation, the maximum treatment period in children is 3 months

2. WHAT INFORMATION IS TO BE KNOWN BEFORE TAKING PEGLAX 10g

List of information necessary before taking the medicine

Occasional constipation:

It may be related to a recent change in hygiene 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 can not be explained by changes in your lifestyle, or in the case of constipation associated with pain, fever or abdominal distension.

Chronic constipation (long term constipation):

It may come from:

- Intestinal disease that requires a physician advice.
- Intestinal dysfunction (imbalance) due to diet habits and hygiene lifestyle.

The treatment includes among others:

- Increase the proportion of vegetal source products in the diet (vegetables, bread, fruits);
- Increase water and juice fruit intake;
- Increase physical activity (sports, walking ...)
- Rehabilitation of defecation reflex.

Do not take PEGLAX 10g if:

You are allergic (hypersensitive) to Macrogol (= P.E.G. = polyethylene glycol) or any of the other excipients.

You have any intestine or colon disease (such as ulcerative colitis, Crohn's disease).

You have abdominal pain of undetermined cause.

You have or suspect a gastrointestinal perforation.

You have or suspect a bowel obstruction (Ileus)

Take special care with PEGLAX 10g:

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's clinical condition.

In case of diarrhoea, attention should be given to patients subject to electrolytic disorders (for example elderly people or patients with impaired hepatic or renal function (patients using diuretics)) and an electrolytic check up should be considered.

This medicine contains Macrogol (=P.E.G. = polyethylene glycol). Very few cases of hypersensitivity reactions (rash, hives or oedema) have been notified.

Taking other medicines

If you use or have recently used another medicine, including medicines obtained without a prescription, tell your doctor or your pharmacist.

Pregnancy and breast feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Inform your doctor if you are pregnant or expect to be or if you are breastfeeding your child.

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to PEGLAX 10g is negligible. PEGLAX 10g can be used during pregnancy.

Breast-feeding

No effects on the breast-feeding newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to macrogol 4000 is negligible; PEGLAX can be used during breast-feeding.

Driving vehicles and using machines

PEGLAX 10g does not affect the ability to drive or 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”.

Important information regarding some components of PEG LAX 10g

PEGLAX 10g does not contain a significant quantity of sugar or polyol; it may be prescribed to diabetics or galactose-free diet patients.

3. HOW TO TAKE PEG LAX 10g

Always take PEG LAX 10g as your doctor has told you if in doubt ask your doctor or your pharmacist.

For oral use.

The usual dose is:

1 to 2 sachets per day, preferably taken as a single dose in the morning.

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 10g occurs within 24 to 48 hours after administering.

Instructions for administering

Each sachet is, before the intake, to be dissolved in a glass of water.

Treatment duration

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

Intestinal transient improvement will be maintained through a healthy lifestyle and dietary measures.

If you take more PEG LAX 10g than you should

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

Excessive liquid loss by diarrhoea or vomiting may require rebalancing electrolytic disorders (i.e. sodium and potassium low blood levels)

If you forget to take PEGLAX 10g

Do not take a double dose to compensate the forgotten dose.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS

Like all medicines, PEGLAX 10g may cause undesirable side effects, but they do not systematically occur with everybody.

- Hypersensitivity reactions: pruritus, urticaria, rash, face oedema, Quincke oedema and an isolated case of anaphylactic shock. You should go straight to hospital if you have difficulty in breathing, start to look flushed, or have any other symptom that you think might mean you are having a serious allergic reaction.
- Diarrhoea, urgent need to go to the toilet or faecal incontinence.
- Abdominal distension and/or pain
- Nausea and vomiting.
- Cases of diarrhoea leading to electrolytes disorders (low blood levels of sodium and potassium: hyponatremia, hypokalemia) and/or dehydration have been reported especially in elderly patients.

Excessive doses can cause diarrhoea, which disappears generally when the dose is reduced or treatment temporarily interrupted. Diarrhoea may cause perianal soreness. If you feel seriously one of the effects mentioned or if undesirable effects not mentioned in this leaflet arise please advise your doctor or pharmacist.

5. HOW TO STORE PEGLAX 10g

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

This medicine does not require special storage conditions

Do not take PEGLAX 10g after the expiry date which is printed on the sachet.

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

Medicines should not be thrown away into the sewers or into the household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

Do not use PEGLAX 10g Powder for Oral Solution if you notice any visible signs of deterioration.

6. FURTHER INFORMATION

What PEGLAX 10g contains

The active substance is: Macrogol 4000

The other ingredients are Saccharin sodium (E954) and Apple flavour

What PEGLAX 10g looks like and contents of the pack

PEGLAX 10g is an almost white powder in a sachet for making up a solution. It is available in packs of 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 EEA under the following names:

Denmark: Casenlax 10g pulver til oral opløsning
Finland: Casenlax 10g jauhe oraaliliuosta varten
France: Casenlax 10g poudre pour solution buvable
Germany: Laxbene 10g Pulver zur Herstellung einer Lösung zum Einnehmen, in Beuteln, für Kinder ab 8 Jahren und Erwachsene
Ireland: Peglax 10g powder for oral solution
Italy: Casenlax 10g polvere per soluzione orale
Netherlands: Casenlax 10g poeder voor drank
Norway: Casenlax 10g pulver til mikstur, oppløsning
Portugal: Casenlax 10g pó para solução oral
Spain: Casenlax 10g polvo para solución oral
Sweden: Casenlax 10g pulver till oral lösning
UK: Peglax 10g powder for oral solution

The last date on which this leaflet has been approved is: August 2018