PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Peglax Neutral

Powder for preparing a suspension

The active ingredient and its concentration:

Polyethylene glycol 3350, 99.973% w/w

Inactive ingredients: see section 6 in the leaflet – "**Additional information**".

Peglax Orange

Powder for preparing a suspension

The active ingredient and its concentration:

Polyethylene glycol 3350, 99.365% w/w

Inactive ingredients: see section 6 in the leaflet – "**Additional information**".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet.

Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

Peglax does not contain sugar and is therefore suitable for diabetics.

1. What is the medicine intended for?

The medicine is intended for treatment of constipation. Peglax softens the stool by increasing the stool water content, causes normal intestinal activity and thus relieves constipation.

Therapeutic class:

Osmotic laxative.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (polyethylene glycol 3350) or to any of the other ingredients this medicine contains (for a list of inactive ingredients see section 6 in leaflet – "Additional information").
- You suffer from an intestinal or colon disease (such as ulcerative inflammation of the large intestine, Crohn's disease).
- You suffer from abdominal pain of undetermined cause.

- You have or suspect you may have gastrointestinal perforation.
- You have or suspect you may have bowel obstruction.

Special warnings regarding the use of the medicine

- The medicine contains polyethylene glycol (Macrogol). Very few cases of hypersensitivity (rash, hives or edema) have been observed.
- The absorption of other medicines may be decreased as a result of an increase in gastrointestinal activity that is caused by polyethylene glycol (see section “Drug interactions”).

Before treatment with Peglax, tell your doctor if:

- You have diarrhea and you are prone to electrolyte balance disorders (for example if you are elderly, if you suffer from impaired liver or kidney function or if you are using diuretics). The doctor will consider monitoring your electrolytes level.

Important information before taking the medicine

Occasional constipation

This constipation may be related to a recent change in your hygiene habits. There are medicines that can be used for short-term treatment of constipation. Consult a doctor in the case of constipation that recently started, which cannot be explained by changes in your lifestyle, or in the case of constipation accompanied by pain, fever or swelling of the abdomen.

Chronic constipation (long-term constipation)

May occur as a result of:

- Intestinal disease that requires medical consultation
- Impaired intestinal function (imbalance) as a result of eating habits and lifestyle

The treatment includes, amongst other things:

- Increasing the percentage of plant-based products in the diet (vegetables, bread, fruit)
- Increasing water intake, including fruit juices
- Increasing physical activity (sport, walking)
- Rehabilitation of defecation reflux (stool)

Children and adolescents

Consult a doctor before administering this treatment to your child in order to exclude any organic cause of constipation. After 3 months of treatment, the doctor should evaluate your child’s clinical condition.

Tests and follow-up

Severe fluid loss due to diarrhea or vomiting may require treatment for rebalancing electrolytic disturbances (such as low blood sodium and potassium levels), and monitoring electrolyte levels should be considered.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

The absorption of other medicines may decrease while using Peglax. The therapeutic effect of medicines with a narrow therapeutic index may be especially affected (such as antiepileptic medicines, Digoxin and immunosuppressant medicines).

Use of the medicine and food

May be taken with or without food.

Pregnancy and breastfeeding

Consult with your doctor or pharmacist before taking any medicine.

If you are pregnant, suspect you are pregnant or if you are breastfeeding, tell your doctor.

Pregnancy

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

Breastfeeding

No effects are anticipated on the breastfeeding newborn/infant since the systemic exposure of the breastfeeding mother is negligible. Peglax can be used during breastfeeding.

Driving and operating machinery

The medicine does not affect your ability to drive or operate machinery.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

Age	**Daily dosage**	**Dissolve in…**	**Number of daily doses**
6 months to 1 year	4 grams	50 ml (quarter of a glass)	Once a day
1 to 4 years	4-8 grams	Dissolve every 4 grams of powder in 50 ml of beverage (quarter of a glass)	The daily dosage can be divided into two doses: morning and evening
4-8 years	8-16 grams	Dissolve every 8 grams of powder in 100 ml of beverage (half a glass)	
From 8 years of age and adults	17 grams	Full glass (230 ml)	Once a day

The effect of Peglax occurs within 24 to 48 hours of administration. With continuous treatment, the intestinal activity will be regular.

Temporary improvement in intestinal activity as a result of the treatment, will be maintained through a healthy lifestyle and dietary measures.

Do not exceed the recommended dose.

A cup for precise dose measurement is enclosed with the product package. Gradations are marked on the sides of the cup to indicate the quantity of powder to be filled in the measuring cup to receive the required dose.

Duration of treatment

If there is no improvement in your condition within a week, refer to the doctor.

The medicine is usually intended for treatment lasting up to 2 weeks, unless otherwise instructed by the doctor.

The duration of treatment in children must not exceed 3 months due to a lack of clinical data regarding more than 3 months of treatment.

How to take the medicine

Dissolve the daily dose in any beverage of choice, such as: water, juice, cold drinks, coffee, tea, milk, baby formula.

Peglax Neutral dissolves completely and quickly in any beverage at any temperature.

Peglax Orange contains flavorings. Adding it to a beverage of another flavor may change the taste of the preparation. To maintain the preparation’s taste, it is advisable to add the powder to water.

Drink the entire dose. It is advisable to take the dose in the morning.

If you accidentally took a higher dosage

You may develop diarrhea, which will disappear after temporarily discontinuing the treatment or after reducing the dosage.

Excessive loss of fluids due to diarrhea or vomiting may require a treatment of electrolytic rebalancing.

If you took an overdose or if a child accidentally swallowed this medicine, go immediately to the emergency room of the hospital and take the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose to compensate for a forgotten dose. Take the next dose at the scheduled time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Peglax may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue use and refer to a hospital immediately if you suffer from:

Breathing difficulties, flushing or any other symptom which may indicate a severe allergic reaction. An isolated case of anaphylactic shock is known.

<u>Side effects reported in adults</u>

Very common side effects (occur in more than 1 user out of 10): abdominal pain, bloated feeling, diarrhea, nausea.

Uncommon side effects (occur in 1-10 users out of 1,000): vomiting, urgent need to go to the toilet, fecal incontinence.

Very rare side effects (occur in less than 1 user out of 10,000): hypersensitivity reaction (itch, hives, rash, face edema, Quincke edema).

Side effects with unknown frequency (effects whose frequency has not yet been determined): electrolyte balance disorders (hyponatremia, hypokalemia) and/or dehydration, particularly in elderly patients, erythema.

<u>Side effects reported in children</u>

Very common side effects (occur in more than 1 user out of 10): abdominal pain, diarrhea.

Uncommon side effects (occur in 1-10 users out of 1,000): vomiting, swelling, nausea.

Side effects with unknown frequency (effects whose frequency has not yet been determined): hypersensitivity reaction.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting of side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

In addition, you can report by emailing the registration holder's Patient Safety Unit at: drugsafety@neopharmgroup.com

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) which appears on the bottle and the carton.

  The expiry date refers to the last day of that month. The expiry date of the preparation after first opening is the same as the expiry date stated on the package.

Storage conditions:

- Store in a cool and dry place, tightly closed, at a temperature below 25°C.
- Do not use the medicine if you notice visible signs of spoilage.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Peglax Neutral (inactive ingredients):

Sucralose 0.027% w/w

Peglax Orange (inactive ingredients):

Ascorbic Acid, Orange Flavor, Sunset Yellow Color, Sucralose 0.025% w/w

What does the medicine look like and what are the contents of the package:

Peglax Neutral is a white powder.

Peglax Orange is a cream powder.

The package contains a 500 ml bottle which contains 250 grams of soluble powder of Peglax.

A cup for precise dose measurement is enclosed with the product package.

Marketing authorization holder and address:

Neopharm Consumer Products Ltd., 6 Hashiloach, P.O.B. 7641, Petach-Tikva 4917001.

Registration numbers of the medicine in the national drug registry of the Ministry of Health:

Peglax Neutral: 144-49-33236-00

Peglax Orange: 144-50-33237-00

Name and address of the manufacturer:

Ben Shimon Floris Ltd., Industrial Park Misgav 20174.

This leaflet was revised in May 2022 in accordance with the Ministry of Health guidelines.