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

This medicine is dispensed without a doctor's prescription

# Peglax Neutral

Powder for oral solution

**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 oral solution

**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.
**Therapeutic class:** Osmotic laxative.
Peglax softens the stool by increasing the stool water content, causes normal intestinal activity and thus relieves constipation.

## 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 suffer from gastrointestinal perforation or suspected gastrointestinal perforation.
- You suffer from bowel obstruction or suspected bowel obstruction.

**Special warnings regarding the use of the medicine**
**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.
The medicine contains polyethylene glycol (Macrogol). Very few cases of hypersensitivity (rash, hives or edema) have been observed, See section 4 "Side effects".
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").

**Essential information before taking the medicine**
Occasional constipation
This constipation may be related to a recent change in your lifestyle. There are medicines that can be used for short-term treatment. 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 amount of fiber in the diet (vegetables, wholegrain bread, fruit)
- Increasing intake of water and fruit juices

Increasing physical activity (such as walking or other exercise)
Rehabilitation of defecation reflux (stool)

**Children and adolescents**
This medicine is not intended for infants under 6 months old. Consult a doctor before administering this treatment to your child in order to exclude any physical (organic) cause of constipation. After three months of treatment, the doctor should evaluate your child's clinical condition.

**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.**
Peglax may delay the absorption of other medicines, which will cause them to be less effective or completely ineffective, especially medicines with a narrow therapeutic index (such as antiepileptic medicines, Digoxin and immunosuppressant medicines).

**Use of the medicine and food**
May be taken with or without food.

**Pregnancy and breastfeeding**
If you are pregnant, suspect you are pregnant, are planning to get 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**
Peglax does not affect your ability to drive or operate machinery.

**3. How should you use the medicine?**

Always use the preparation according to the doctor's instructions. 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 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**

The recommended duration of treatment for children, is up to three months. If longer treatment is required, consult with your doctor.

**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 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, stomachache, and vomiting, which will disappear after temporarily discontinuing the treatment or after reducing the dosage.

If you suffer from severe diarrhea or severe vomiting, contact a doctor as soon as possible since you may need treatment to prevent loss of electrolytes as a result of fluid loss.

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 every time 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.

**Severe side effect**

The most severe side effect is an allergic reaction (hypersensitivity), including itching, rash, facial edema (swelling of the face), angioedema of the lower layers of the skin (Quincke's disease), urticaria (hives), and anaphylactic shock. The reported effect is very rare (may appear in less than one in 10,000 users) in adults and its incidence is unknown (not yet determined) in children. **If you notice one of these reactions, immediately stop using the medicine and see emergency medical assistance.**

Side effects reported in adults

In general, the side effects that were reported are few and fleeting and are mainly associated with the digestive system.

**common side effects** (occur in less than 1 in 10 users): abdominal pain, bloated feeling, diarrhea, nausea.

**Uncommon side effects** (occur in less than 1 in 100 users): vomiting, urgent need to go to the toilet, fecal incontinence.

**Very rare side effects** (occur in less than 1 in 10,000 users): hypersensitivity reaction (itch, hives, rash, face edema).

**Side effects with unknown frequency** (effects whose frequency has not yet been determined): electrolyte balance disorders (low levels of sodium and potassium in the blood: hyponatremia, hypokalemia) and/or dehydration caused by severe diarrhea, particularly in the elderly, erythema (redness).

Side effects reported in children

**Common side effects** (occur in less than 1 in 10 users): Abdominal pain, diarrhea (may cause pain in the rectal area).

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

**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 marketing authorization 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.

**Name and address of the manufacturer:**

Ben Shimon Floris Ltd., Industrial Park Misgav 20174.

**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

Revised in October 2025.