

Patient Package Insert in Accordance with the Pharmacists Regulation
(Preparations) - 1986

This medicine is to be supplied without physician's prescription

PEGLAX NEUTRAL

Soluble Powder for Preparing a Drink
without Flavoring

Composition:

Active agent: Polyethylene Glycol 3350 - 99.973% w/w

The product packaging includes a measuring cup for exact dosing.

Non-active ingredients: see paragraph 6: "**Further Information**".

PEGLAX ORANGE

Soluble Powder for Preparing
an Orange Flavored Drink

Composition:

Active agent: Polyethylene Glycol 3350 - 99.365% w/w

The product packaging includes a measuring cup for exact dosing.

Non-active ingredients: see paragraph 6: "**Further Information**".

Read the entire package insert carefully before using this medication. This insert contains essential information of this medicine. If you have more questions, turn to your doctor or pharmacist.

This medicine is not usually specified for infants under the age of 6 months.

Use it wisely. Consult a pharmacist if you require further information.

If your condition does not improve within a week, consult a doctor.

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

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

1. What PEG LAX is used for?

The medicine is intended for treating constipation.

PEGLAX (polyethylene glycol) is laxative that belongs to the stool softeners and stool volume expanders family that creates osmotic pressure in the gastrointestinal tract. **PEGLAX** softens the stool by increasing the stool water content, causing normal intestinal activity, thus relieving constipation.

Therapeutic group:

2. Before using this medicine

Do not use PEGLAX if:

You are hypersensitive (allergic) to the active ingredient Polyethylene Glycol 3350 or to any of the other ingredients of the medicine. (For a full list of the non-active ingredients see paragraph 6 "Further information").

You are suffering from bowel obstruction, severe inflammatory bowel disease (such as Crohn's disease) or chronic bowel dysfunction.

If you are suffering or have suffered in the past from gastrointestinal perforation or abdominal pain of unclear cause.

Special precautions concerning the use of this drug

Before starting treatment with PEGLAX, tell your doctor if:

- You are pregnant or breastfeeding.
- You are suffering from kidney disease, irritable bowel, nausea and vomiting, or if you noticed sudden change in the frequency of your intestinal activity that continues more than two weeks.

The treatment of constipation using any drug will only be done while changing eating habits and lifestyle (see also in paragraph 3 in the leaflet "How to use this medicine?" under the sub- title: "How can you contribute to the success of the treatment?").

If you are sensitive to any type of food or medicine, inform the doctor before taking this medicine. In addition, do not use for other purposes, such as "cleaning the body" etc.

- In case of diarrhea, special attention is required for patients with a predisposition to electrolyte balance disorders (such as elderly people or patients with impaired liver or kidney function (patients using diuretics)), and electrolyte monitoring should be considered.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, vitamins or herbal remedies.

Tell your doctor or pharmacist especially if you are using any of the following medicines: Other laxatives, Digoxin (for the heart).

PEGLAX and food

May be taken on a full or empty stomach.

For directions for use see paragraph 3 in the leaflet: "How to use this medicine?".

Pregnancy and lactation:

If you are pregnant or breastfeeding, consult a doctor or pharmacist before starting the treatment with **PEGLAX**.

3. How to use this medicine?

You should check with your doctor or pharmacist if you are not sure.

Dosage and directions for use:

The usual dosage unless otherwise instructed by the doctor:

Age	Daily dosage	Dissolve in...	Number of daily doses
6 months to 1 year	4 grams of powder	50 ml drink (a quarter of a glass)	Once a day
1-4 years	4-8 grams of powder	Every 4 grams of powder are dissolved in 50 ml of drink (a quarter of a glass)	Daily dosage may be divided into two doses: morning and evening
4-8 years	8-16 grams of powder	Every 8 grams of powder are dissolved in 100 ml of drink (half a glass)	
From 8 years and adults	17 grams of powder	A full glass (230 ml)	Once a day

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

Directions for use:

Do not use this medicine in its original dry form. Dissolve the daily dose in any preferred beverage, such as: water, juice, cold beverage, coffee, tea, milk, infant formula, etc.

After drinking the dose, it is advisable to drink another cup of liquids.

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 original taste.

To maintain the original taste, it is advisable to add the powder to water.

Drink the whole dose immediately after the preparation. It is advisable to take the dose in the morning.

May be taken on a full or empty stomach.

After stools become soft, dosage may be reduced.

Do not exceed the recommended dose.

This medicine is not usually specified for infants under the age of 6 months.

If your condition does not improve within a week, consult a doctor.

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

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

Attention:

From the beginning of treatment with **PEGLAX**, the first bowel movement is usually expected to occur after 24 to 48 hours. Later in the treatment, intestinal activity will be regular.

If you accidentally taken higher dosage than normal, you should:

If you have taken an overdose, or if a child accidentally swallowed the medicine, proceed immediately to your physician or to a hospital emergency room and bring the package of the medicine with you.

How can you contribute to the success of the treatment?

If you are suffering from constipation, it is advisable to change your eating habits and lifestyle. Enrich your diet with fiber rich food, make sure to drink satisfactory volumes and engage in physical activity. These changes may contribute to normal intestinal activity. Make sure to drink fluids during the day, which will help soften stools.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have other questions regarding the use of this medicine, please consult your physician or pharmacist.

4. Side effects

Like all medicines, **PEGLAX** can cause side effects in some of the users. Don't be alarmed to the list of side effects. It may be that you won't experience any of them.

Side effects requiring special attention:

Acute diarrhea: discontinue treatment and contact a doctor.

Cases of diarrhea causing electrolyte balance disorders (i.e. low levels of sodium and potassium: hyponatremia, hypokalemia) and/or dehydration have been reported, especially in elderly patients.

Excessive doses may cause diarrhea, which usually resolves with dose reduction or temporary treatment discontinuation. Diarrhea may cause anal pain.

If you notice rectal bleeding or if the nausea, swelling or abdominal pain worsen: discontinue treatment and contact a doctor.

Take extra care in patients who are sensitive to changes in their body salt balance (change in body electrolytes), such as: liver patients, kidney patients or people who are taking diuretics.

Allergic reactions (manifesting in rash) - (rare): discontinue treatment and contact a doctor.

Chest pain, difficulties breathing (rare): discontinue treatment and contact a doctor immediately.

Additional side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, such as: nausea, sensation of swelling, contractions, diarrhea (more common in adult) and/or flatulence.

Most of the adverse reactions are very mild to mild and usually disappear after a few days. If they continue, discontinue use of the medicine.

Side effects and drug interaction in children:

Parents must report to the attending doctor about any other medicine that is being administered to their child!

In the event that you experience side effects not mentioned in this leaflet, or if one of the side effects mentioned gets serious contact your doctor immediately.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid Poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use this drug after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. The expiry date after first opening is identical the expiry date stated on the outer package.
- **Storage:**
Store in a cool and dry place, under 25°C, well closed in the original package. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only.
Do not store different medications in the same package.

6. Further Information:

In addition to the active ingredient this medicine also contains:

PEGLAX NEUTRAL (non-active ingredients): Sucralose 0.027% w/w.

PEGLAX ORANGE (non-active ingredients): Sucralose 0.025% w/w, Ascorbic Acid, Orange Flavor, Sunset Yellow Color.

What is the appearance of PEG LAX and what is the package content:

The products packaging includes a 500 ml bottle containing a 250 gr of soluble powder, of **PEGLAX**.

The products packaging includes a measuring cup for exact dosing.

Registration Holder name and address: Neo-life Health-Care Ltd., 6 Hashiloach Street, P.O.B 7063, Petach-Tikva 4917001.

Registration number of the drug in the national drugs registry of the Ministry of Health:

PEGLAX NEUTRAL: 144-49-33236-00

PEGLAX ORANGE: 144-50-33237-00

Manufacturer name and address: Ben Shimon Floris Ltd., Industrial Park Misgav 20174.

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