Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed without a doctor's prescription.

Normalax

Powder for oral solution

Active ingredient and quantity:
polyethylene glycol 3350 100%
Inactive ingredients and allergens: The medicine does not contain inactive ingredients and allergens.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

You must use this medicine according to the instructions in the dosage section in this leaflet.
Consult your pharmacist if you need additional information. You must contact a doctor if your symptoms worsen or do not improve.

1. What is this medicine intended for?

The medicine is intended for the treatment of constipation. Normalax softens the stool by increasing the water content in the stool, promotes normal bowel activity, thereby relieving constipation.
Therapeutic group:
Osmotic laxative.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (polyethylene glycol 3350).
- 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.

Special warnings regarding the use of this medicine
Before treatment with Normalax, tell your doctor if:

- You have diarrhea and are prone to electrolytic disorders (for example, if you are elderly, have impaired hepatic or renal function, or use diuretics). The doctor will consider monitoring electrolytes.
- The medicine contains polyethylene glycol (Macrogol). Very few cases of hypersensitivity reactions (rash, urticaria or edema) have been observed.

The absorption of other medicines may decrease due to the increase in the activity of the gastrointestinal tract caused by polyethylene glycol (see section ‘Drug interactions’).

Essential information before taking the medicine
Occasional constipation
It may be related to a recent change in hygiene habits. There are medicines that can be used for short-term treatment. Consult 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 distension.
Chronic constipation (long-term constipation)
May occur as the result of:
- Intestinal disease that requires a doctor's advice.
- Intestinal dysfunction (imbalance) due to eating habits and lifestyle.

The treatment includes, among others:
- Increasing the proportion of plant-based products in the diet (vegetables, bread, fruit).
- Increasing water and fruit juice intake.
- Increasing physical activity (sports, walking).
- Rehabilitation of defecation reflex (stool).

Children and adolescents
Consult your doctor 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.

Tests and follow-up
Severe fluid loss due to diarrhea or vomiting may require rebalancing electrolytic disorders (i.e., 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 nonprescription medications and dietary supplements, tell your doctor or pharmacist. Especially if:
The absorption of other medicines may decrease while Normalax is being used. The therapeutic effect of medicines with a narrow therapeutic index may be especially affected (for example, antiepileptic medicines, Digoxin and immunosuppressant drugs).

Using this medicine and food
May be taken with or without food.

Pregnancy and breastfeeding
Consult your doctor or pharmacist before using any medicine at all.
If you are pregnant, suspect you may be pregnant or if you are breastfeeding, tell your doctor.

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

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

Driving and using machines
The medicine does not affect your ability to drive or operate machines.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
The recommended dosage is usually:

Age	Daily dosage	Dissolve in...	No. of daily doses
6 months to 1 year	4 grams	50 ml (1/4 cup)	Once daily
1 year to 4 years	4-8 grams	Each 4 grams of powder is dissolved in 50 ml of beverage (1/4 cup)	The daily dosage can be divided into two doses: morning and evening
4-8 years	8-16 grams	Each 8 grams of powder is dissolved in 100 ml of beverage (1/2 cup)	
From 8 years and adults	17 grams	A full cup (230 ml)	Once daily

The effect of Normalax occurs within 24 to 48 hours of administration. With continued treatment, intestinal activity will be regular.
Transient improvement in intestinal activity will be maintained through a healthy lifestyle and dietary measures.

Do not exceed the recommended dose.

If using the bottle package, there is a cup on the bottle cap to measure the dose accurately.
There are marked scales on both sides of the measuring cup.

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

Sachets are for use in children over the age of 8 and adults only. The package contains a 17 gram dose.

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

Normalax does not contain added flavoring and aroma. It is colorless and dissolves rapidly and completely in any beverage, at any temperature.

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

If you have accidentally took a higher dose
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 electrolytic rebalancing.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the required time, do not take a double dose to make up for the forgotten one. Take the next dose at the regular time and consult your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicines. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Normalax may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Discontinue use and refer to a hospital immediately if you are suffering from:
Breathing difficulties, flushing or any other symptom which may be indicative of a severe allergic reaction. An isolated case of anaphylactic shock is known.

Side effects reported in adults

Very common side effects (appear in more than 1 in 10 users)
Abdominal pain, feeling of bloating, diarrhea, nausea.

Uncommon side effects (appear in 1-10 in 1,000 users)
Vomiting, urgent need to go to the toilet, fecal incontinence.

Very rare side effects (appear in less than 1 in 10,000 users)
Hypersensitivity reaction (pruritus, urticaria, rash, face edema, Quincke edema).

Side effects of unknown frequency (the frequency of these effects has not yet been established)
Electrolyte disorders (hyponatremia, hypokalemia) and/or dehydration, particularly in elderly patients, erythema.

Side effects reported in children

Very common side effects (appear in more than 1 in 10 users)
Upset stomach, diarrhea.

Uncommon side effects (appear in 1-10 in 1,000 users)
Vomiting, bloating, nausea.

Side effects of unknown frequency (the frequency of these effects has not yet been established)
Hypersensitivity reaction.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Report side effects:
You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! Keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants and by doing so prevent poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the bottle/carton. The expiry date refers to the last day of that month.

Storage conditions:

- Store below room temperature (25°C).
- Do not use this medicine if you notice visible signs of spoilage.
- Shelf-life after first opening of the bottle: 12 months.

6. Additional information

Inactive ingredients: None.

What the medicine looks like and contents of the pack:
White to creamy-while powder.
There are 2 types of packages:

- A bottle containing 70 or 240 grams of powder.
- Sachets containing 17 grams of powder (each sachet is a single dose).

Not all pack sizes may be marketed.

Manufacturer and registration holder: Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
142 15 32012

This leaflet was revised in January 2024 according to MOH guidelines.