

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% w/w

Inactive ingredients and allergens in this medicine: 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.

Therapeutic group:

Osmotic laxative.

Normalax softens the stool by increasing the water content in the stool, promotes normal bowel activity, thereby relieving constipation.

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

Talk to your doctor before treatment with Normalax.

If you develop diarrhea following treatment with Normalax, you may be at risk of developing electrolytic disorders (a decrease in certain salts in the blood). You are more likely to be at risk, if you are elderly, have liver or kidney problems or are taking diuretics. If you are one of these people and you develop diarrhea, you should see your doctor to have your electrolyte levels checked with a blood test.

The medicine contains polyethylene glycol (macrogol). Very few cases of hypersensitivity reactions (rash, urticaria or edema) have been observed. See section 4 'Side effects'.

The absorption of other medicines may temporarily 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 your lifestyle. 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:

- An increase in the proportion of fiber in the diet (vegetables, wholegrain bread, fruit).
- Increasing water and fruit juice intake.
- Increasing physical activity (such as walking or other forms of sport).
- Rehabilitation of defecation reflex (stool).

Children and adolescents

The medicine is not intended for babies below the age of 6 months.

A sachet is intended for use in children over the age of 8 years.

Consult your doctor before administering this treatment to your child, in order to exclude any physical (organic) cause of constipation. After three months of treatment, your doctor should evaluate your child's clinical condition.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Normalax may delay the absorption of other medicines, making them less effective or ineffective, especially medicines with a narrow therapeutic index (for example, antiepileptics, Digoxin and immunosuppressant drugs).

Using this medicine and food

May be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant, suspect you may be pregnant or are planning a pregnancy 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

Normalax 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...	Number 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)	The daily dosage can be divided into two doses: morning and evening
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.

A sachet is intended for use in children over the age of 8 and in adults only. Each sachet 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, abdominal pain and vomiting which will disappear after temporarily discontinuing the treatment or after reducing the dosage.

If you suffer from severe diarrhea or vomiting, you should contact a doctor as soon as possible as you may require treatment to prevent loss of salts (electrolytes) due to fluid loss.

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.

Serious side effects

The most serious side effects are allergic (hypersensitivity) reactions, including itching, rash, face edema (swelling of the face), angioedema (rapid swelling of the deep layers of the skin), urticaria (hives) and anaphylactic shock. Its frequency has been reported as very rare (may affect up to 1 in 10,000 users) in adults and as unknown (not yet determined) in children. **If you notice any of these reactions, stop taking this medicine immediately and seek urgent medical assistance.**

Side effects in adults

Generally, reported side effects have been minor and temporary and have mainly concerned the gastrointestinal system.

Common side effects (appear in up to 1 in 10 users)

Abdominal pain, feeling of bloating, diarrhea, nausea.

Uncommon side effects (appear in up to 1 in 100 users)

Vomiting, urgent need to pass stool, fecal incontinence.

Very rare side effects (appear in up to 1 in 10,000 users)

Hypersensitivity reaction (pruritus, urticaria, rash, face edema).

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

Electrolyte disorders (low blood levels of sodium and potassium: hyponatremia, hypokalemia), dehydration caused by severe diarrhea, especially in elderly patients, erythema.

Side effects in children

Common side effects (appear in up to 1 in 10 users)

Abdominal pain, diarrhea (may cause perianal soreness).

Uncommon side effects (appear in up to 1 in 100 users)

Vomiting, bloating, nausea.

Excessive doses can cause diarrhea, abdominal pain and vomiting which generally disappear when the dose is reduced or treatment temporarily interrupted.

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.

Reporting 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 sachet or carton. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 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-white powder.

There are two types of packages:

- A bottle containing 70 or 240 grams of powder. The package contains a measuring cup.
- 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:

142-15-32012-00

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