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

The medicine is dispensed
without a doctor's prescription

REGULAX

Powder for oral solution

Active ingredient and its concentration:
polyethylene glycol 3350, 99.973% w/w.
Inactive ingredients: See section 6 of this leaflet: "**Additional information**".

Read the entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
Use the preparation according to the instructions in the section on dosage in this leaflet.
If you need further information, consult with the pharmacist. You must contact a doctor if your symptoms worsen or do not improve.

Regulax does not contain sugar, and is therefore suitable for diabetics.

1. What is the medicine intended for?

The medicine is intended for the treatment of constipation. Regulax softens the stool by increasing the water content in the stool, and promotes normal bowel activity, thereby relieving constipation.

Therapeutic group:
Osmotic laxative.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (polyethylene glycol 3350) or to the additional ingredient (sucralose) contained in the medicine.
- 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 Regulax, 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 electrolyte level.
- 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 constipation that recently started, 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 a result of:

- Intestinal disease that requires medical consultation
- Intestinal dysfunction (imbalance) due to eating habits and lifestyle

The treatment includes, among others:

- Increasing the percentage of plant-based products in the diet (vegetables, bread, fruit)
- Increasing water and fruit juice intake
- Increasing physical activity (sports, walking)
- Rehabilitation of the 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 of 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 pharmacist.
The absorption of other medicines may decrease while Regulax 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).

Use of the medicine and food

May be taken with or without food.

Pregnancy and breastfeeding

Consult your doctor or pharmacist before using any medicine.

If you are pregnant, think you may be pregnant or if you are breastfeeding, tell your doctor.

Pregnancy

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

Driving and using machines

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

3. How should you use the medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation. The usual dosage is generally:

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

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

Do not exceed the recommended dose.

A cup for accurate dose measurement is enclosed 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.

Treatment duration –

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

Method of administration

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

Regulax dissolves rapidly and completely in any beverage and at any temperature.

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

If you have accidentally taken 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 electrolytic rebalancing.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of medicine 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 dose each time you take a medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, use of Regulax may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from 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's 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):
Abdominal pain, 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 a side effect occurs, 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 can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

Additionally, a report can be sent to the license holder's Patient Safety Unit to the following email address:
drugsafety@neopharmgroup.com

5. How should the medicine be stored?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants to avoid 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 and carton.
  The expiry date refers to the last day of that month. The expiry date after first opening is identical to the expiry date imprinted on the package.

Storage conditions:

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

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sucralose 0.027% w/w

What the medicine looks like and contents of the pack:
Regulax is a white powder.
A Regulax package includes a 500 ml bottle containing 250 g of soluble powder.
A cup for accurate dose measurement is enclosed in the product package.

License holder and address:
NEOPHARM CONSUMER PRODUCTS LTD,
6 Hashiloach St., P.O.B. 7641 Petach - Tikva 4917001

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

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
150-25-33953-00

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