

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

The medicine is dispensed with a doctor's prescription only

EASYLAX Tablets

The active ingredient and its amount:

Each tablet contains: Yellow Phenolphthalein 120 mg

For a list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is not usually intended for infants and children under 12 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

- The medicine is a laxative and is intended for the relief of constipation.

Therapeutic group: Laxatives.

2. BEFORE USING THE MEDICINE:

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient (Yellow Phenolphthalein) or to any of the other ingredients in the medicine.
- in the event of intestinal obstruction or chronic intestinal dysfunction.

Special warnings regarding use of the medicine:

- Warning! Prolonged use may cause a dependency on laxatives such as this one and diarrhea.
- Do not use in children under 12 years of age without consulting the doctor.
- This preparation is intended only for constipation that lasts for a number of days. Lack of bowel activity for one or two days does not justify its use. In addition, do not use this medicine for other purposes such as "body cleansing" and the like.

Before treatment with EASYLAX, tell the doctor if:

- you are pregnant or breastfeeding.
- you suffer, or have suffered in the past, from impaired function of the heart or kidney, from acute abdominal pain, from diabetes, from rectal bleeding, from signs of appendicitis (e.g., unidentified abdominal pain, nausea and vomiting).
- you are sensitive to any type of food or medicine.

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- other laxatives.
- antacids.

Pregnancy and breastfeeding:

There is no evidence that the use of EASYLAX Tablets is harmful during pregnancy or breastfeeding. However, as with other medicines, EASYLAX Tablets should not be taken for the first 12 weeks of pregnancy. If you are pregnant or breastfeeding, consult with the doctor or pharmacist before using medicines.

Driving and operating machinery:

There is no known effect of the medicine on these activities.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and manner of treatment shall be determined by the doctor only. The usual dosage is generally:

For adults and children above 12 years of age: Half up to one and a half tablets at bedtime.

Use of this medicine is not recommended for children under 12 years of age.

Do not exceed the recommended dose.

- Swallow with water, milk or juice.
- The tablets may be halved or crushed immediately before swallowing.
- Do not store the halved or crushed tablets.

- Make sure to drink liquids during the day to help soften the stool.

Wait at least two hours between taking this medicine and taking other oral medicines.

The preparation usually works within 4-8 hours but sometimes more time is required (up to 3 days).

If there is no improvement in your condition within a week, refer to the doctor.

Do not use the medicine frequently or for a prolonged period without consulting the doctor.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. An overdose may cause diarrhea accompanied by loss of fluids and electrolytes, particularly potassium. These symptoms should be treated. There is a possibility that you will develop a medical condition in which there will be no colonic function.

If you forgot to take the medicine, wait until the next evening and take the next dose at its scheduled time. Do not take a double dose to make up for a forgotten one.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

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

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of EASYLAX Tablets may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop using the medicine and refer to the doctor if you suffer from:

- abdominal pain or cramps.
- allergic reactions such as: rash, swelling of the face or neck, or breathing difficulties.
- heart problems.
- breathing problems.
- kidney damage.
- signs of electrolyte loss (fatigue or weakness, increased heart rate, confusion). These symptoms may appear following an overdose.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you should consult with the doctor.

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 in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at room temperature, up to 25°C.
- Do not dispose of medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Magnesium Carbonate, Powdered Agar, Docusate Sodium, Strong Ginger Tincture, Povidone, Magnesium Stearate, Pigment Blend, Chocolate Flavour, Saccharin Sodium, Methylparaben.

Each tablet contains approximately 5.5 mg sodium.

What does the medicine look like and what are the contents of the package:

The package contains a bottle with 20 brown tablets in it.

License Holder, manufacturer and address:

Sam-On Ltd., 25 Ha'avoda St., Bat-Yam.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 35 84 22447

This leaflet was checked and approved by the Ministry of Health in May 2014.