Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is to be supplied by physician's prescription only

AGIOLAX®
Granules

Active ingredients:
Each 100 gr of granules contain:
Ispaghula husk 2.2 gr
Ispaghula seed 52 gr
Senna 6.74 - 13.15 gr

For the list of inactive ingredients – see section "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or to the pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

What is this medicine intended for?

The medicine is intended for short-term treatment of constipation.

Therapeutic group:
Ispaghula husk (a common name for plantago husk) and Ispaghula seeds are bulk laxatives which swells upon contact with water.
Senna reacts directly on the intestines and stimulates them.

Before using this medicine

Do not use this preparation if:
- You are sensitive (allergic) to Senna, Ispaghula husk, Ispaghula seed or to any of the other ingredients that this medicine contains (please see "Additional information")
- You suffer from abnormal narrowing in the gastrointestinal tract
- You suffer from intestinal obstruction
- You suffer from diabetes mellitus which is difficult to control
- You suffer from acute inflammatory intestinal diseases, e.g. Crohn's disease (inflammatory disease in the gastrointestinal tract), ulcerative inflammation of the colon or appendicitis
- You suffer from abdominal pain of unknown origin
- You suffer from acute dehydration with water and electrolyte losses
- Patient's age is under 12 years of age

Special warnings regarding the use of this medicine
- Prolonged use of laxatives may lead to exacerbation of intestinal activity.
- This medicine should be used only if no therapeutic effect has been obtained by a dietary change or use of bulk laxatives only.
- If the medicine is taken by adult incontinent person, avoid prolonged contact of the skin with the feces by changing diapers.
- Do not use this medicine frequently or for a long period, without consulting a physician.

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, inform your physician or pharmacist. In particular inform the physician or the pharmacist if you are taking:
- In cases of chronic use or inappropriate use, potassium deficiency may potentiate the action of medicines such as glycosides for the treatment of heart problems (e.g. digoxin), and may affect the activity of medicines used for the treatment of arrhythmia (e.g. quinidine)
- Potassium loss may be exacerbated if diuretics (thiazides), cortisone or adenocorticosteroids or licorice root are taken concomitantly
- Absorption of medicines from the gastrointestinal tract into the blood system may be retarded
- Diabetic patients treated with insulin may require adjustment of the insulin dose

Children
Do not use in children below the age of 12 years.

Taking Agiolax and food
Take Agiolax after the evening meal.

Pregnancy and breastfeeding
Consult a physician or pharmacist if you are pregnant.
During the first 3 months of pregnancy, the medicine should be used only if constipation cannot be resolved by a dietary change or with use of bulk laxatives agents.
Degradation products of Senna have a laxative effect and may pass into breast milk in small quantities.
No laxative effect on breast-fed babies has been observed.

Driving and using machines
Agiolax has no known influence on your ability to drive or use machines.

Important information about some of the medicine's ingredients
Each teaspoon (5 gr) of Agiolax granules contains 0.88 - 1.2 gr of sucrose. If you are diabetic or suffer from intolerance to certain sugars, consult the physician prior taking Agiolax.

How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.
The dosage and manner of treatment will be determined only by the physician.

Directions for use:
- Place the dry Agiolax granules on your tongue and swallow them whole with a large quantity of water (at least 250 ml)
- Do not chew or crush Agiolax granules
- No mixing is required
- Take Agiolax half an hour to 1 hour after taking any other medicine

- The recommended dosage for adults and adolescents over 12 years of age, 1 - 2 teaspoons (5 or 10 gr) of Agiolax to be swallowed once daily with an abundant amount of liquid, after the evening meal
- The ideal dosage is the lowest dosage resulting in soft but firm stool
- Effect of the medicine is experienced about 8 to 12 hours after medicine intake
- If you do not experience any relief of symptoms after 7 days of treatment with Agiolax, consult your physician
- Do not take Agiolax for a period exceeding 1 to 2 weeks without consulting your physician
- Assure to measure the dose by using the enclosed teaspoon

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to the physician or a hospital emergency room and bring the medicine package with you.
In case of an overdose, the following symptoms may appear: painful intestinal cramps, acute diarrhea which may cause loss of fluids and minerals.
If you forgot to take the medicine at the scheduled time, take the forgotten dose immediately; **do not take a double dose.**
Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult the physician or the pharmacist.

Side effects

As with any medicine, the use of Agiolax may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Very rare side effects:
- Abdominal cramps; in case of the occurrence of this side effect, reduce the dosage of Agiolax
- Change of the urine color to red. This change is not harmful
- Oesophagus obstruction
- Allergic reactions

Prolonged use or use at high dosage (abuse) may lead to disorders of water and electrolyte balance. Diarrhea may lead to loss of potassium. Potassium loss may lead to disorders of cardiac function and muscle weakness, especially upon using Agiolax concomitantly with medicines such as: cardiac glycosides (digoxin), diuretics, cortisone or adrenocorticosteroids. Long term use may cause appearance of blood and protein in the urine. Furthermore, pigment accumulation in the gastrointestinal tract may occur, which is reversible following discontinuation of Agiolax treatment.

If any side effect appears, if any side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult the physician.
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

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Use Agiolax within 6 months of package opening.
- Ensure closing the granule container tightly after each use.
- Do not store above 25°C.

Additional information

- In addition to the active ingredients (Ispaghula husk, Senna, Ispaghula seed), the medicine also contains:
  Sucrose, Talc, Gum Arabic (Acacia), Iron oxides (yellow, red, black), Liquid paraffin, Hard paraffin, Peppermint oil, Caraway oil, Sage oil.
- Each teaspoon (5 gr) of Agiolax contains 2.6 gr of Ispaghula seed, 0.11 gr of Ispaghula husk and 0.34-0.66 gr of Senna.
- What does the medicine look like and what are the contents of the package:
  Agiolax contains brown granules and is supplied in packages of 100 gr, 200 gr.
- Marketing Authorization Holder and his address: MegaPharm Ltd., P.O.B. 519, Hod Hasharon 4510501.
- Manufacturer and his address: Madaus GmbH, Koln, Germany.
- This leaflet was checked and approved by the Ministry of Health in September 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140-20-22366.