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

This medicine is dispensed with a doctor's prescription only

Agiolax, Granules

Active ingredients

Each 100 g of granules contain:

Ispaghula husks 2.2 g
Ispaghula seed 52 g
Senna 6.74 - 13.15 g
Each teaspoon (5 gr) of **Agiolax** contains 2.6 g ispaghula seed, 0.11 g ispaghula husk and 0.34-0.66 g senna, equivalent to 15mg hydroxyanthracene glycosides calculated as sennoside B.

For the list of inactive ingredients and allergens in the medicine: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

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

1. What is this medicine intended for?

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

Therapeutic group: Laxatives.
Ispaghula husk (a common name for a plantago plant husk) and **ispaghula** seeds are bulk laxatives which swell upon contact with water.
Senna acts directly on the intestines and stimulates their activity.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to ispaghula husk, ispaghula seed, senna or to any of the other ingredients in this medicine (see section 6 'Additional information').
- You have a blockage or narrowing of the gastrointestinal tract or bowel (ileus, intestinal obstruction or fecal impaction).
- You have diabetes which is difficult to control.
- You have appendicitis or suffer from any bowel disorders, such as acute inflammatory bowel diseases, e.g. Crohn's disease (inflammatory disease of the gastrointestinal tract), ulcerative colitis or enlarged bowel (megacolon).
- You have abdominal problems of unknown origin, such as abdominal pain, nausea or vomiting.
- You have acute dehydration.
- In children under 12 years of age.
- You have a sudden change in bowel habits that has persisted for more than 2 weeks.
- You have undiagnosed rectal bleeding for which you don't know the cause, or blood in the stool.
- You have already taken another laxative and are still constipated.
- You have difficulty in swallowing or any throat problems.
- You have paralysis or lack of muscle tone in the bowel wall (atony).
- You have naturally occurring reduced gut motility (i.e., the speed with which material moves through your gut has always been slow).
- You have kidney or heart problems.
- You are pregnant or breastfeeding.

Special warnings about using this medicine

- Take each dose of **Agiolax** with 1-2 glasses of water or a similar drink, such as milk or fruit juice. Taking **Agiolax** without enough fluids may cause blockage of the throat and esophagus with choking and intestinal obstruction. Symptoms can be chest pain, vomiting, difficulty in swallowing or breathing. If you experience any of the above symptoms, get medical attention immediately (see section 3 'How to use this medicine').
- Do not exceed the dose stated in this leaflet.
- Make sure you drink enough fluids while taking **Agiolax**. This will help with constipation.
- To decrease the risk of gastrointestinal obstruction (ileus), medicines reducing bowel motility (e.g. opioids) should only be used under medical supervision.
- **Agiolax** contains potent allergens. As a consequence, after oral use or contact with the skin, **Agiolax** may cause hypersensitivity (allergic) reactions (see section 4 'Side effects').
- Overuse or prolonged use of laxatives may cause:
  - Exacerbation of intestinal activity.
  - Disturbance of electrolyte and mineral balance in the body. Sodium, potassium, magnesium and phosphorus are electrolytes and minerals that are present in very specific amounts necessary for proper functioning of the nerves and muscles in the body (including those of the bowel and heart). Interference with this balance may cause incorrect functioning of these vital organs.
  - Severe dehydration, which may cause tremor, weakness, blurry vision, fainting, kidney damage, and, in extreme cases, death. Dehydration usually requires medical treatment.
  - Overuse of laxatives may cause the colon to stop reacting to the usual dose of laxatives, so that larger and larger doses of laxatives may be needed to produce bowel motility.
  - Laxative dependency.
- This medicine should be used only if no therapeutic effect has been obtained by physical activity, a dietary change or use of bulking agents only.
- If the medicine is taken by adults with fecal incontinence, avoid prolonged contact of the skin with the feces by changing diapers more frequently.

Before treatment with Agiolax, tell your doctor or pharmacist if:

- You are weak or elderly (you will need to be monitored while taking **Agiolax**).
- You have intestinal obstruction (hard, dried stool with abdominal pain, nausea and vomiting).
- You have been informed by your doctor that you have narrowing of the intestines or reduced bowel motility.
- You need to use laxatives every day for constipation. Do not use laxatives for a long time without your doctor's instruction. Using stimulant laxatives (such as senna) may occasionally slow down the bowel and aggravate constipation (lazy bowel).

Is the medicine effective for weight loss?

Laxatives (including senna) are not effective for weight loss. They do not reduce the absorption of calories or food. They can cause watery stools (diarrhea), abdominal cramps and dehydration. Dehydration can erroneously seem like weight loss.

Drug interactions:

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

- Diabetes patients treated with insulin, adjustment of the insulin dose may be required.
- Do not take with medicines which may reduce bowel motility (e.g. codeine and morphine).
- Do not take **Agiolax** within half an hour to 1 hour before and after taking other medicines.
- Mineral or vitamin ***B12*** supplements.
- Medicines for heart failure or heart rhythm (e.g. cardiac glycosides, antiarrhythmic medicines e.g. ***quinidine*** and medicines inducing ***QT*** prolongation).
- Blood thinning medicines such as ***warfarin***.
- Carbamazepine for epilepsy.
- Lithium for bipolar disorder.
- Medicines for thyroid problems - your doctor may need to change the dose of the thyroid hormones you are taking.
- Water tablets (***diuretics)***.
- Certain steroids used for inflammation (***adrenocorticosteriods***).
- Liquorice root.
- Long term use of laxatives may increase the side effects of some medicines you are taking.

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

Taking this medicine and food
Take **Agiolax** after the evening meal.

Pregnancy, breastfeeding and fertility
Do not take **Agiolax** if you are pregnant or breastfeeding.

Driving and using machines
Agiolax has no known effect on the ability to drive or operate machines.

Important information about some of this medicine's ingredients
Agiolax contains sucrose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking the medicine.

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. Only your doctor will determine your dose and how you should take this medicine.

Instructions for use:

- Before taking this product, sit in an upright position.
- **Agiolax** granules should be placed dry on the tongue and swallowed whole with plenty of water, warm milk, fruit juice or similar fluids (at least 250 ml).
- Do not chew or crush **Agiolax** granules.
- No mixing is required.
- Take **Agiolax** half an hour to 1 hour before or after taking any other medicine.
- The recommended dosage for adults and adolescents over 12 years of age: 1-2 teaspoons of **Agiolax** (5 or 10 g) once daily, in the evening after the evening meal, with plenty of fluids.
- Do not take this medicine immediately before bedtime.
- The ideal dosage is the lowest dosage resulting in soft but not loose 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 doctor.
- Do not take **Agiolax** for a period exceeding 1 to 2 weeks without consulting your doctor.
- Ensure measuring the dose using the teaspoon supplied with the medicine.
- Drink about 5-10 glasses of fluid every day while you are taking this medicine.

Do not exceed the recommended dose.

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

If you have accidentally taken a higher dose
If you take too much **Agiolax** or take **Agiolax** for too long, it may be harmful and the following symptoms may appear:

- Lazy bowel, where the muscle in the bowel becomes "too relaxed" (decrease in contractions). This means that bowel emptying occurs less often. This can lead to long term constipation.
- Imbalance of fluids and salts in the body. This can affect the tightness of muscles (such as the bowel muscles) and the salts in the blood.
- Deficiency of potassium in the blood (hypokalemia). This may cause tiredness, dizziness, muscle weakness and irregular heartbeat.
- Dehydration, which may be manifested by sensation of thirst, fainting, headaches and reduced urination.

If you forget to take the medicine at the scheduled time, take the forgotten dose immediately. Do not take a double dose.
Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take 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

Like with all medicines, using **Agiolax** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.
Stop the treatment and contact your doctor immediately if you experience:
Abdominal pain, rectal bleeding or any change in the stool, such as blood in the stool.
If you experience any of the following side effects, stop the treatment and contact your doctor immediately, as these side effects may be signs of an allergic reaction:

- Anaphylactic reaction – severe and potentially life-threatening reaction with symptoms such as feeling lightheaded or faint, breathing difficulties, ***wheezing***, fast heartbeat, skin rash, confusion, anxiety or loss of consciousness***.***
- Difficulty breathing including shortness of breath.
- Nausea and vomiting.
- Rhinitis (nasal obstruction or congestion).
- ***Conjunctivitis***.
- Chest tightness, ***wheezing***.
- Asthma or worsening of asthma symptoms.
- A skin rash resembling **hives** or **nettle rash** – itchiness, swelling, local redness or more widespread redness.

Contact your doctor if:

- The side effects/symptoms persist or worsen while taking **Agiolax**.
- There is no bowel movement within 3 days of initiation of **Agiolax** use.
- You need to take laxatives every day or if abdominal pain persists.

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

- Flatulence (wind) - may occur for a short time after initiation of **Agiolax** use.
- Nausea and vomiting.
- Abdominal pain, abdominal cramps and runny stool, in particular in patients with irritable bowel. These symptoms may also occur due to overuse of **Agiolax**. In this case, dose reduction may be necessary.
- Swollen abdomen, difficulty swallowing and blockage in the throat or gut (hard, dried stool collected in the rectum and anus) may occur, particularly if fluid intake is insufficient.
- Chronic use may lead to ***albuminuria*** and ***hematuria***, which is presence of albumin or red blood cells in the urine.
- Yellow or red-brown discoloration of urine may occur, which is harmless.
- Chronic use may cause pigmentation of the gastrointestinal tract, which usually recedes when medicine intake is discontinued.

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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. 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 external package. The expiry date refers to the last day of that month.
- Use **Agiolax** within 6 months of opening the package.

Storage conditions

- Ensure closing the granule container tightly after each use.
- Store below 25°C.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Sucrose, talc, acacia, iron oxides E172 (yellow, red, black), liquid paraffin, hard paraffin, peppermint oil, caraway oil, sage oil.

- **What the medicine looks like and contents of the pack:**

  Agiolax contains Small-grained, medium brown granules with aromatic odour and is available in packs of 100 g, 200 g.
- **Registration holder's name and address:** Megapharm Ltd., 15 Hatidhar St., Ra'anana, Israel.
- **Manufacturer's name and address:** Madaus, 51101 Koeln, Germany**.**
- This leaflet was revised in June 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 140-20-22366

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