

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

This medicine is dispensed without a doctor's prescription

**Agiocur**

**Granules**

**Active ingredient**

Each 100 g of granules contain:

Ispaghula seed 65.0 g

Ispaghula husk 2.2 g

Each measuring spoon (5g) of **Agiocur** contains 3.25 g of ispaghula seed, 0.11 g of ispaghula husk and about 0.9 g sucrose.

For the list of inactive ingredients and allergens in this 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.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Consult your doctor if your symptoms of illness get worse or do not improve within 3 days.

**1. What is this medicine intended for?**

The medicine is intended for regulation of bowel function (constipation or diarrhoea).

**Therapeutic group:** bulking agents.

**Medical activity:**

Psyllium hydrophilic mucilloid is produced from the seeds and husk of plantago and ispaghula. It is rich in dietary fibres and belongs to the group of bulking agents absorbing water at a quantity several times larger than their own volume. Thereby **Agiocur** increases faecal volume and stimulates bowel activity.

Note: Persistent bowel movement irregularity (beyond 3 days) requires evaluation by a doctor.

**2. Before using this medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to ispaghula husk, ispaghula seed, peppermint oil or to any of the other ingredients in this medicine (see section 6 'Additional information').
- You have swallowing problems and throat problems;
- There is a sudden change in your bowel movement habits lasting more than 2 weeks;
- After intake of a laxative not followed by defecation;
- You have abnormal faecal impaction (a large, hard mass of stool that gets stuck in the colon or rectum);

- You have rectal bleeding which was not thoroughly evaluated;
- You have abnormal stenoses in the oesophagus, cardia (orifice of the stomach) or gastrointestinal tract;
- You have or are at risk of developing gastrointestinal obstruction (ileus) or megacolon syndrome.

### **Special warnings about using this medicine**

- **Before treatment with Agiocur, tell your doctor if** you suffer from unclear problems in the abdomen, abdominal pain, nausea and vomiting. These symptoms may be a sign indicating that you have or are at risk of developing gastrointestinal obstruction (ileus). In this case, do not take **Agiocur**.
- Take **Agiocur** with an abundant amount of liquid, i.e. 200 ml of water (1 glass of water) for one measuring spoon of **Agiocur** (equivalent to 5 g). Administration of **Agiocur** without sufficient amount of liquid may cause swelling of the fibres and oesophagus blockage, leading to a sensation of choking. If you experience chest pain, vomiting, difficulties in swallowing and breathing after taking **Agiocur**, consult a doctor immediately.
- Intestinal obstruction (ileus) may occur due to insufficient intake of liquid.
- In order to reduce the risk of intestinal obstruction, medicines reducing bowel motility (such as opioids) should be taken only under medical supervision.
- If the constipation does not resolve within 3 days, if you experience abdominal pain or have irregular bowel activity, stop using **Agiocur** and seek medical advice.

### **Children and adolescents**

No sufficient information on the use of **Agiocur** in children is available; therefore, the medicine should not be given to children under 6 years of age without consulting a doctor.

### **Elderly**

Treatment of patients and elderly people with a weakly condition must be performed under a doctor's supervision.

### **Interactions with other medicines:**

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

- Thyroid medicines - may be taken with **Agiocur** only after consulting a doctor, because the doctor may need to change the dose of the thyroid hormones that you are taking.  
A decrease in the activity of thyroid hormones cannot be excluded even if **Agiocur** intake does not occur concomitantly with the thyroid medicine intake.
- Other medicines taken concomitantly with **Agiocur** intake. The absorption of medicines taken concomitantly, like minerals (e.g. calcium, iron, lithium and zinc), vitamins (vitamin B12), cardiac glycosides and coumarins may be delayed.  
Therefore, ensure an interval of half an hour to one hour between **Agiocur** intake and intake of other medicines.
- Anti-diabetic medicines. For diabetes patients, adjustment of the anti-diabetic medicine dosage regimen may be required. A doctor should be consulted.

Note for diabetics: A single dose of **Agiocur** (5 g) is equivalent to 0.9 g sucrose (sugar), equivalent to 0.07 bread units (BU).

### **Using this medicine and food:**

Take **Agiocur** after supper (at least one hour before bedtime).

### **Pregnancy, breastfeeding, and fertility:**

If you are pregnant, breastfeeding, think you are pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before using **Agiocur**.

If a dietary change is not helpful and use of a laxative is necessary, bulk-forming laxatives such as **Agiocur** should be preferably used before using other active laxative substances.

### **Driving and using machines:**

**Agiocur** has no known effect on the ability to drive or operate machines.

### **Important information about some of this medicine's ingredients**

**Agiocur** 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. One measuring spoon (5 g) contains 0.9 g sucrose (sugar). This information should be considered for patients with diabetes.

**Agiocur** may be harmful to teeth (tooth decay).

## **3. How to use this medicine?**

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

### **Dose:**

Unless instructed otherwise by a doctor, the recommended dose is usually:

#### Children aged 6-12 years:

One measuring spoon (5 g) after supper and at least 1 hour before bedtime. Do not take immediately before bedtime.

#### Adolescents aged 12 years and older and adults:

##### Constipation:

2 measuring spoons (5 g each) of **Agiocur** after supper (at least 1 hour before bedtime). Do not take immediately before bedtime.

If necessary, take one extra measuring spoon (5 g) of **Agiocur** before breakfast.

##### Tendency to diarrhoea:

It is recommended to start with a dose of 2 measuring spoons (5 g each) of **Agiocur** 3 times per day for 1-3 days. Subsequently take 1 measuring spoon (5 g) of **Agiocur** 3 times per day as needed.

Swallow the granules with an abundant amount of liquid (1-2 glasses of water) without chewing.

The daily liquid intake should be 1-2 litres.

Do not give this medicine to children under 6 years of age without consulting a doctor.

If there is no improvement within 3 days, contact your doctor or pharmacist.

**Mode of administration:**

Do not take **Agiocur** immediately before bedtime; take the medicine in standing position.

Swallow the granules with plenty of water (1-2 glasses).

Do not chew. Mixing is not required.

**Attention!**

Ensure measuring the dose with the measuring spoon provided with the medicine.

Wait for half an hour to one hour between taking this medicine and taking other medicines (orally). The onset of medicine action is 12-24 hours after its intake.

**How can you assist in treatment success?**

If you use the medicine for treatment of constipation, ensure drinking plenty of fluids throughout the day, which will help in stool softening (1-2 liters). In case of constipation, the medicine usually stimulates bowel activity within 12 hours, but sometimes more time is required (up to 3 days).

**Do not exceed the recommended dose.**

**If you have accidentally taken a higher 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.

In case of overdose, the number and severity of side effects such as abdominal pain, flatulence and sensation of fullness may be increased. Drink an abundant amount of liquid. A doctor should be consulted as to whether any countermeasures are necessary.

**If you forget 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 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:**

As with any medicine, using **Agiocur** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

- Complaints existing prior to treatment initiation, such as abdominal bloating or sensation of fullness, may worsen during the initial days of treatment, but will disappear as treatment is continued. Especially in cases of insufficient fluid intake, swelling of the abdomen (tympanites) may occur, and there will be a risk of intestinal obstruction (ileus), oesophageal obstruction and constipation.
- Ispaghula husk contains substances which may cause sensitivity (allergy) after **Agiocur** intake or upon skin contact.  
Symptoms of allergic reactions may include running nose, reddening of the eyes, breathing difficulties, skin reactions, itching and, in isolated cases, anaphylactic shock (a sudden allergic reaction which affects the entire body and may lead to a life-threatening shock reaction).
- Nausea and vomiting.

In sensitive patients, peppermint oil may cause hypersensitivity reactions (including respiratory distress).

**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](http://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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

#### Storage conditions

- Store this medicine below 25°C.
- Use this medicine within 6 months after opening the package.
- Ensure closing the granule container tightly after each use.

### **6. Additional information**

- **In addition to the active ingredient, this medicine also contains:**

#### **Inactive ingredients:**

sucrose, talc, acacia (gum arabic), iron oxide yellow (E172), liquid paraffin, hard paraffin, titanium dioxide (E171), peppermint oil, iron oxide red (E172), caraway oil, sage oil.

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

**Agiocur** contains light brown sugar coated granules.

**Agiocur** is supplied in packs of 100 g and 200 g. Each pack contains a measuring spoon. Not all pack sizes may be marketed.

- **Registration holder's name and address:** Megapharm Ltd., 15 Ha'tidhar St., Ra'anana, Israel

- **Manufacturer's name and address:** Madaus GmbH, Koeln, Germany
- This leaflet was revised in October 2023 according to Ministry of Health guidelines.
- Registration number of the medicine in the Ministry of Health National Drug Registry: 062-97-25777

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