

THIS LEAFLET WAS DETERMINED BY THE MINISTRY OF HEALTH AND ITS CONTENT WAS CHECKED AND APPROVED BY IT IN MAY 2012

PATIENT PACKAGE LEAFLET IN ACCORDANCE WITH THE  
PHARMACISTS REGULATIONS (PREPARATIONS 1986)

Read this package leaflet in its entirety  
before using this medicine

## Agiocur Granules

### Composition:

#### Active ingredients:

##### Each 100 grams of granules contains:

Seeds of Plantago ovata 65.0 g

Ispaghula husks 2.2 g

Each teaspoon (5 grams) contains approximately 0.9 grams of sucrose.

#### Inactive ingredients:

Sucrose, Talc, Gum Arabic (Acacia), Iron Oxide yellow (E172), Liquid paraffin, Hard Paraffin, Titanium Dioxide (E171), Iron Oxide red (E172), Peppermint Oil, Caraway Oil, Sage oil.

#### Therapeutic group:

Bulk-forming.

#### Medical activity:

Psyllium hydrophilic mucilloid is produced from the seeds and husk of plantago and ispaghula and rich in dietary fibers. Psyllium hydrophilic mucilloid belongs to a bulk-forming category absorbing water several times larger than its basic volume. By this **Agiocur** will enlarge the volume of the feces and enhance bowel activity. This medicine is intended to regulate bowel activity (constipation or diarrhea).

Note: persistent and irregular bowel movement (over three days) requires consultation with a doctor.

#### When should this product not be used?

Do not use this medicine if there is a known sensitivity to Plantago or to one of the components of this medicine, do not take this medicine if you have difficulties swallowing and throat problems; in case of bowel obstruction; dilation of the large intestines; chronic dysfunction of the intestines; sudden change in normal bowel movement that persist for more than two weeks after taking a laxative, which does not result in passing stool; rectal bleeding that has not been thoroughly investigated; unusual narrowing of the gastrointestinal system or diabetes which is difficult to control.

**Do not use this medicine without consulting your physician before initiation of therapy** if you are suffering from a strong stomach ache, difficulties swallowing or signs of appendicitis (such as stomach ache, nausea or vomiting from unidentified reasons). If you are a diabetic or if you are suffering from malabsorption of sugars, as this medicine contains sugar (each spoon contains about 0.9 grams of sucrose).

#### Warnings:

**Prolonged use in case of constipation may lead to laxatives dependency (such as this). Do not use this medicine often or for prolonged periods without consulting your doctor.**

If you are sensitive to any food products or medicines, your doctor must be notified before taking this medicine. Severe and persistent diarrhea, which does not respond to **Agiocur** requires a physician's examination to establish the cause; in addition, the electrolyte level in your blood must be checked (especially potassium levels). Taking **Agiocur** without taking sufficient amounts of fluids may cause swelling of the fibers and create a block in the oesophagus, which will cause a choking sensation. If you experience chest pain, vomiting,

difficulties in swallowing and breathing after taking **Agiocur**, you must consult your doctor at once.

Treatment of elderly and weak patients must be done under a physician's supervision. This medicine is intended only for the treatment of constipation or diarrhea that lasts for a few days. Lack of bowel activity that persists only for one or two days does not justify using this medicine. In addition, this medicine must not be used for other purposes such as "body cleansing"; etc.

#### Drug interactions:

Please inform your attending physician if you are taking or have recently taken any other medicines, including medicines that do not require a prescription and food supplements, in order to avoid risks or inefficacy resulting from drug interactions, especially relating to the following food supplements and medicines: minerals (such as calcium, iron and zinc), lithium for bipolar disorder, vitamins (vitamin B12), cardiac glycosides (such as digoxin), blood thinning medicines (such as warfarin), carbamazepine (for epilepsy), cumarines and thyroid gland hormones, bulk laxatives and medicines taken to stop diarrhea by delaying bowel movements (such as loperamide and opiates). Diabetic patients treated with insulin may need an adjustment to their insulin dose. Your doctor may consider changing your dose if you are taking medicines for the treatment of the thyroid gland.

#### Side effects:

In addition to the desired effect of this drug, some side effects may appear during treatment. Existing conditions such as a swollen sensation in your stomach, gas and feeling full may worsen during the first few days of treatment, but disappear with the continuation of it.

#### Side effects that require special attention:

Allergic reactions such as rash, redness, itching and shortness of breath: stop treatment and refer to a doctor or a hospital at once!

Side effects of an unknown frequency:

blockage of the esophagus, throat or intestines (experienced as hard stool at the rectum especially if there is not enough fluid intake), stomach pain or swollen stomach. If you notice any of the side effects worsen, side effects that have not been mentioned in this leaflet or if there has been a change to your general feeling, you must consult your doctor at once.

#### Side effects and drug interactions that appear in children:

Parents must inform the physician of any side effects and additional medicines that are being administered to the child.

#### Dosage:

Accepted dose, in the lack of a different instruction from a physician: Children between the ages of 6-12:

1 teaspoon (of 5 grams) after supper and at least one hour before bedtime. Do not take immediately before bedtime.

Adolescents from the age of 12 and adults:

#### Constipation:

2 teaspoons (5 grams each) of **Agiocur** after supper (at least one hour before bedtime), Do not take immediately before bedtime.

If needed, take an additional teaspoon (5 grams) of **Agiocur** before breakfast.

#### Diarrhea:

It is recommended to begin with a dose of 2 teaspoons (5 grams each) of **Agiocur**, three times a day for 1-3 days. Afterwards take one teaspoon (5 grams) of **Agiocur**, three times a day, as needed. Swallow the granules with a large amount of liquid (1-2 glasses of water), without chewing. The daily fluid intake must be between 1-2 liters of water.

Do not exceed the recommended dose.

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

If there has been no improvement within 3 days, refer to your doctor or pharmacist.

#### Pregnancy and lactation:

Consult your physician or pharmacist before use, if you are pregnant or think you may be pregnant.

This medicine can be used during pregnancy.

If a dietary change is not helpful, it is first recommended to use bulk laxatives, such as **Agiocur** before using other active ingredient laxatives. In any case, pregnant or breast feeding women must first consult their physician or pharmacist before taking medicines.

#### Pay attention!

Make sure the dose is measured with the added measuring spoon. Wait half an hour to an hour between taking this medicine and other medicines (per os). The effect of this medicine starts within 12-24 hours from the time it was taken.

#### Directions for use:

Do not take **Agiocur** immediately before bedtime; take this medicine in a standing position. Swallow the granules with a large amount of water (1-2 glasses). Do not chew. There is no need for mixing.

#### How can you contribute to the success of this treatment?

Make sure you drink a large amount of fluids during the day, if you are using this medicine for the treatment of constipation. This will help to soften the stool (1-2 liters). In constipation this medicine will usually stimulate bowel movement within 12 hours, however sometimes a longer period of time is needed (up to three days).

#### Avoid Poisoning!

This medicine and all other medicines must be stored in a safe place out of the reach of children and/ or infants. This will help avoid poisoning. If you have taken an overdose or if a child had accidentally swallowed from this medicine, refer to a hospital's emergency room immediately and bring the package of this medicine with you. Do not induce vomiting unless specifically instructed by your doctor! Do not take medicines in the dark! Check the label each time you take a medicine. Wear eye glasses if you need them.

#### Storage:

Store below a temperature of 25°C. Use this medicine within six months after first opening. Even if stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of this medicine! In case of doubt, consult the pharmacist who dispensed this drug to you. Do not store different drugs in the same package.

#### Registration number:

062 97 25777 00

#### Manufacturer:

Madaus GmbH, Kologne, Germany.

#### Registration holder:

MegaPharm Ltd, P.O. Box 519, Hod Ha' Sharon 45105.