SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Agiocur

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances :
5 g of granules (= 1 measuring spoon) contain:

Ispaghula seed	3.25 g
Ispaghula husk	0.11 g

Excipients with known effect:
5 g of granules contain about 0.9 g sucrose.

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Granules,
Light brown sugar-coated granules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for the relief of habitual constipation in patients requiring a high fibre regimen.

4.2 Posology and method of administration

For oral administration.

Method of administration:
Agiocur should be placed dry on the tongue and swallowed whole, without chewing or crushing, with a sufficient quantity of liquid (at least 150 ml for each 5 gr measuring spoon), i.e. water, milk, fruit juice or similar aqueous liquid. The fluid intake must be maintained; a daily fluid intake of 1-2 litres is recommended.
Agiocur should be taken at least ½ to 1 hour before or after intake of other medicines. The effect starts 12-24 hours later.

Posology:
Adolescents over 12 years of age, adults, elderly:
Two heaped 5 gr measuring spoons to be taken every evening after a meal (at least one hour before going to bed) and if necessary, one extra heaped 5 gr measuring spoon before breakfast.
Warning: not to be taken immediately prior to bed-time.

Children from 6 to 12 years of age:
One heaped 5 gr measuring spoonful daily to be taken every evening after a meal (at least one hour before going to bed).
Warning: not to be taken immediately prior to bed-time.

Pregnant women:
Dose as for adults.

Duration of use:
If the constipation does not resolve within 3 days, a doctor or pharmacist should be consulted.
See also section 4.4 Special warnings and precautions for use.

4.3 Contraindications

Agiocur should not be taken in case of:
- Hypersensitivity to the active substances, peppermint oil or to any of the excipients listed in section 6.1.
- Patients suffering from difficulties in swallowing or from various throat disorders
- Abnormal faecal impaction (faecal stones)
- Sudden change of bowel movement habits lasting for more than 2 weeks
- After intake of a laxative not followed by defecation
- Rectal bleedings not further clarified
- Abnormal stenoses in the esophagus, the cardia or in the gastrointestinal tract
- Imminent or existing ileus or megacolon syndrome.

4.4 Special warnings and precautions for use

When taking Agiocur, attention should be paid to taking an abundant amount of fluid, i.e. 200 ml of water (1 glass of water) for one measuring spoon of Agiocur (equivalent to 5 g).

Intake of Agiocur without a sufficient amount of liquid may cause it to swell and block the throat or oesophagus causing the risk of suffocation.

In order to reduce the risk of ileus, ispaghula seed/ispaghula husks should be used in combination with other medicinal products known to inhibit bowel motility (such as opioids) under medical supervision ONLY.

If the constipation does not resolve within 3 days, if abdominal pain should occur or in case of irregular bowel movement, use of Agiocur should be discontinued and a doctor shall be consulted.

Treatment of debilitated patients and the elderly has to occur under supervision of a doctor.

Agiocur contains sucrose.
It is not recommended to use Agiocur in patients with rare hereditary fructose intolerance, glucose-galactose-malabsorption syndrome or sucrose-isomaltase deficiency.
One measuring spoon contains 0.9 g sucrose (sugar). This should be taken into account in patients with diabetes mellitus. Agiocur may be harmful to the teeth (tooth decay).
If thyroid hormones are taken concomitantly dose adjustment could be necessary.

Children and adolescents
No adequate data are available on the use of Agiocur in children; therefore, this product should not be administered to children under 6 years of age.

4.5 Interactions with other medicinal products and other forms of interaction

Absorption of drugs taken concomitantly such as minerals (e.g. calcium, iron, lithium, zinc), vitamins (vitamin B12), cardiac glycosides and coumarins from the intestine could be retarded. That is why an interval of half an hour to one hour should be adhered to between the intake of Agiocur and other drugs.

Diabetic patients should take Agiocur under medical supervision only since an adaptation of the anti-diabetic therapy may be required.

A decrease of the activity of thyroid hormones cannot be excluded even if administration of Agiocur will not occur concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of Agiocur in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.
Use in pregnancy and during lactation may be considered, if this should be necessary and a change in diet is not successful. Bulk laxatives should be used prior to other purgatives.

Fertility
There are no adequate studies from the use of Agiocur with regard to fertility.

4.7 Effects on ability to drive and use machines

Results of investigations are not available. To date, no relevant events have been reported.

4.8 Undesirable effects

The frequencies of undesirable effects are categorised as follows:

Very common:	≥ 1/10
Common:	≥ 1/100 - < 1/10
Uncommon:	≥ 1/1.000 - < 1/100
Rare:	≥ 1/10.000 - < 1/1.000
Very rare:	< 1/10.000
Not known:	Frequency cannot be assessed on the basis of the available data.

For Agiocur, the following undesirable effects are known:

Pre-existing complaints such as bloating or sensation of fullness may become more pronounced during the first days of treatment, but will diminish as treatment is continued. In particular in

case of insufficient fluid intake swelling of the abdomen (tympanites) may occur, and there will be a risk of ileus, oesophageal obstruction as well as constipation. Frequency is unknown.

Flatulence may occur with the use of Agiocur; this generally disappears in the course of the treatment. The frequency is not known.

Plantago ovata (ispaghula) husks/seeds contain allergic substances. Therefore, upon oral administration or upon skin contact Agiocur may cause hypersensitivity reactions such as rhinitis, conjunctivitis and bronchospasm up to anaphylactic reactions. Cutaneous symptoms including exanthema and/or pruritis have also been reported. Frequency is unknown.

Nausea and vomiting can occur. Frequency is unknown.

In sensitized patients, peppermint oil can cause hypersensitivity reactions (including respiratory distress).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

4.9 Overdose: Symptoms, contingency measures and antidote

In the event of overdose, the symptoms known as undesirable effects such as abdominal pain, flatulence and sensation of repletion can be increased. Adequate fluid intake should be maintained, and management should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:
Herbal bulk laxative for bowel regulation

ATC code: A06AC51

Agiocur is a plant-based bulking and swelling agent. By virtue of its swelling properties Agiocur regulates disturbed intestinal function in the following way:

a) Softening of hard stools:
Binding of part of the physiological fluids in the gastrointestinal tract prevents excessive re-absorption of water in the colon.
The stool volume is increased, peristaltic activity stimulated and the passage of intestinal contents shortened.

b) Solidification of watery stools:
The swelling agents bind excessive quantities of fluid, thus increasing the viscosity and volume of intestinal contents and lengthening the transit time.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

In acute toxicity studies on mice, rats and dogs, maximum oral doses of 10 g/kg (= 25 times the maximum dose administered to humans) did not produce any toxic effects.

In the light of these results and on the basis of the general rating in the Federal Register of the Food and Drug Administration, Psyllium preparations are classified as "safe and effective in amounts usually taken orally".

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose; Talc; Acacia; Iron oxide yellow (E172); Liquid paraffin;
Hard paraffin; Titanium dioxide (E171); Peppermint oil; Iron oxide red (E172), Caraway oil; sage oil);

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Always keep the container properly closed after use.
Store below25 °C.
After first opening of the container Agiocur is stable for 6 months.

6.5 Nature and contents of container

Composite container, Inner lacquer PVDC/PVCA with an inner lid and screw lid made of polypropylene.

Pack size:100 g and 200 g
Not all pack sizes may be marketed.
A measuring spoon (5g of granules) is added to all multi-dose containers.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

Megapharm Ltd., 15 Ha'Tidhar street, Ra'anana, Israel.

8. MARKETING AUTHORISATION NUMBER(S)

062-97-25777

9. MANUFACTURER

MADAUS GmbH, Germany
51101 Koeln, Germany

10. DATE OF REVISION OF THE TEXT

Revised in October 2023 according to MOHs guidelines.