Patient Package Insert according to Pharmacists' Regulations (Preparations)- 1986

This medicine can be sold without a doctor's prescription

Agnucaston
Film-coated tablets

Active ingredient and its quantity in dosage unit:

Each film-coated tablet contains:

Agnus castus fruit dry extract (7-11:1) 4.0 mg; extraction solvent: Ethanol 70 % (V/V)

For a list of all inactive ingredients and allergens in the medicine - see section 6.

For important information about some of the ingredients of the medicine- see section 2.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

You should take the medicine Agnucaston according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need any further information. You should refer to the doctor in case the illness symptoms worsen or do not improve after 3 months.

1. What is the medicine intended for?

The medicine Agnucaston is intended for:

- Treatment of premenstrual syndrome characterized by the following symptoms: fatigue, breast swelling and sensitivity, pain in the abdominal region, mood swings, restlessness, joint and muscle pain.
- Treatment of breast pain and sensitivity (Mastodynia).

The medicine Agnucaston is intended for women 18 years of age and above.

Therapeutic group: herbal medicine for the treatment of menstrual complaints.

2. Before using the medicine

☒ Do not use the medicine:

- If you are hypersensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine. Additional ingredients are listed in section 6.
- If you are pregnant.

Special warnings regarding the use of this medicine:

☐ The use of the active ingredient contained in this medicine may mask the symptoms of a prolactin secreting tumor of the pituitary gland.

Inform your doctor in case:

☐ You suffer or suffered in the past from an oestrogen-sensitive malignant tumor.

☐ You take medicines of the dopamine agonists, dopamine antagonists, if you are treated with oestrogen hormones or anti-oestrogen medicines.

☐ Your symptoms worsen following the use of the medicine Agnucaston.

☐ You have suffered in the past from a pituitary disorder. According to the available information, the active ingredient contained in the medicine Agnucaston acts on the hormone-secreting hypothalamic-pituitary axis.

Children and adolescents:

Do not use the medicine Agnucaston in children and adolescents under 18 years of age since there is insufficient information regarding the use of this medicine in this age group.

Drug interactions:

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. Potential interactions between the medicine Agnucaston and medicines of the dopamine agonists, dopamine antagonists, medicines that contain oestrogens or anti-oestrogen medicines cannot be ruled out.

Use of this medicine and food: the medicine Agnucaston may be taken with or without food.

☐ **Pregnancy, breast-feeding and fertility:**

Pregnancy: Since there is insufficient information regarding use of the medicine Agnucaston in pregnant women, do not use the medicine while pregnant.

Breast-feeding: Since it is not known if the components of the active ingredient dissolve or are excreted into the breast milk and there is no sufficient information regarding the safety of use of the medicine while breast-feeding, endangerment of the breastfed infant cannot be ruled out. Therefore, do not use the medicine Agnucaston while breast-feeding

Fertility: No specific studies have been performed regarding the influence of the medicine on fertility.

☐ **Driving and use of machinery:** no studies have been performed to assess the effect of the medicine on the ability to drive or use machinery.

☐ **Important information about some of the ingredients of this medicine:** The medicine Agnucaston contains lactose. Consult a doctor before using the medicine if you have an

intolerance to certain sugars.
Information for diabetics: a single film-coated tablet of Agnucaston contains an average of 0.1 grams of carbohydrate.

3. How should you use this medicine?

Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The usual recommended dosage for women 18 years of age and above is:
One film-coated tablet once a day.
There is no information regarding the exact dosage for patients who suffer from impaired kidney or liver function.

Do not exceed the recommended dose.

Duration of treatment with the medicine: the medicine Agnucaston should be taken for 3 months without interruption, also during menstruation. You should consult the doctor if you take the medicine Agnucaston for more than 3 months.

How to take the medicine: swallow the film-coated tablet in whole with a sufficient amount of drinkable liquid (e.g. a glass of water).
Crushing/halving/chewing: there is no information on crushing. Do not split the tablet. Swallow the tablet in whole with water.

If you have accidentally taken an overdose: so far, no incidents of overdose as a result of taking the medicine Agnucaston have been reported. If you have accidentally taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Your doctor will decide whether it is necessary to take any action.

If you forgot to take this medicine at the intended time, do not take a double dose. Take the next dose at the regular time and consult your doctor. Proceed with the treatment as recommended by your doctor. Even if there is an improvement in your health, do not stop the treatment without consulting your doctor.

If you stop taking the medicine: Make sure to take the medicine consecutively for 3 months, also during menstruation. Discontinuation of the treatment is usually not accompanied by withdrawal phenomena or special symptoms.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

As with any medicine, the use of Agnucaston may cause side effects in some users.
Do not be alarmed while reading the list of side effects, you might not suffer from any of them.
Since only single cases of side effects have been reported, the precise frequency of side effects as a result of the use of the medicine Agnucaston cannot be evaluated. The following side effects may appear during the course of the treatment:
Side effects that require special attention: Stop taking the medicine and refer immediately to a doctor or a hospital emergency room at the first sign of hypersensitivity (allergic reaction) such as swelling of the face, shortness of breath or swallowing difficulties.
Additional side effects that may appear: allergic skin reaction (including rash, urticaria), headache, dizziness, gastrointestinal complaints (including nausea and abdominal pain), acne, menstrual irregularities.
If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, refer to your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the home page of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects.
Additionally, side effects can be reported to the company Dr. Samuelov Importing and Marketing at the e-mail address:
drugsafety@drsamuelov.co.il

5. How should you store the medicine?

Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (Exp. Date) stated on the carton or the blister. The expiry date refers to the last day of that month.
Storage conditions: store at a temperature below 30ºC.

6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:
Ammonio methacrylate copolymer (type A), ferric

oxide yellow (E172), indigo carmine laquer (E132), potato starch, lactose monohydrate, magnesium stearate, macrogol 6000, microcrystalline cellulose, povidone 30, colloidal anhydrous silica, talc, titanium dioxide (E171), sorbic acid, sodium hydroxide.

What the medicine looks like and contents of the package: the medicine Agnucaston looks like a green-blue, round, biconvex, film-coated tablet with a dull surface and no score line. The film-coated tablets are packed in blisters, which are packed in carton boxes.

Package size: The medicine Agnucaston comes in carton boxes containing 2 blisters with 15 film-coated tablets in each blister, 30 film-coated tablets in each box.

Registration holder and importer: Dr. Samuelov Importing & Marketing Ltd., Company ID 512260944 P.O.B 2486, Ra'anana 4365007. Tel.: 09-7483769, e-mail address: info@drsamuelov.co.il.

Manufacturer: Bionorica SE, Neumarkt 92318, Germany.

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Drug registration number in the national medicine registry of the Ministry of Health: 159-79-34979-00.

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