

KIRA PREM FILM-COATED TABLETS

THR 29860/0003

UKPAR

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KIRA PREM FILM-COATED TABLETS

THR 29860/0003

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Cassella-med GmbH & Co. KG a Traditional Herbal Registration Certificate for the traditional herbal medicinal product Kira Prem Film-coated Tablets (Traditional Herbal Registration number: 29860/0003). This product is available without prescription and can be bought from pharmacies and other outlets.

Kira Prem Film-coated Tablets are used for the relief of premenstrual symptoms. The tablets' active ingredient comes from the fruit of the plant *Vitex agnus castus* L., also known as the chaste tree. This registration is based exclusively upon evidence of traditional use of Agnus castus fruit as a herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.

KIRA PREM FILM-COATED TABLETS

THR 29860/0003

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal remedy Kira Prem Film-coated Tablets to Cassella-med GmbH & Co. KG on 7 October 2009. This product is on the general sales list (GSL).

The application was submitted under Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme.

This product consists of film-coated tablets containing 4 mg of Agnus castus fruit extract. The product is used for the relief of premenstrual symptoms.

The Herbal Medicines Advisory Committee (HMAC) considered Agnus castus fruit acceptable for the General Sales List for internal use.

This THR is based exclusively on evidence of traditional use of Agnus castus fruit. The recommended dose is one tablet daily.

The data supplied by the applicant demonstrate 30 years of traditional use of Agnus castus fruit in the European Community. A satisfactory review of the available safety data on Agnus castus fruit has also been provided, together with an expert safety report supporting the proposed product.

PHARMACEUTICAL ASSESSMENT REPORT

HERBAL SUBSTANCE

Manufacture

The herbal substance is the fruit of the plant, *Vitex agnus castus* L., which belongs to the Verbenaceae family. This plant is indigenous to the whole of the Mediterranean region as far as Western Asia. The fruit is collected from the wild, mainly from Morocco.

Ripe fruits are collected manually from August to September and dried under natural conditions before being stored protected from light.

The information provided on the collection of the plant starting material is considered to be acceptable and assurance has been given that cultivation and harvesting are performed according to Good Agricultural and Collection Practice (GACP).

Characterisation

The fruits are globular to oblong 4-seeded drupes, black-brown to olive-black, with a diameter of 3 – 5 mm. The fruit is surrounded two-thirds to three-quarters in a cup-like fashion by the greenish-grey fine-tomentose calyx. The calyx ends up in 4 – 5 short three-cornered teeth. Some of the fruits still have the fruit stalk, which is about 1 mm long. The fruit is quadrilocular and each loculus contains an oblong adipose seed. The fruits have an aromatic sage-like odour and a sharp pepper-like taste.

Control of Herbal Substance

The starting material is stated to comply with the monograph "Agnus-castus-Früchte" DAC (Deutscher Arzneimittel-Codex i.e. the German Pharmaceutical Codex, a supplementary pharmacopoeia to the European and German Pharmacopoeia). The DAC specifications are comparable to the Pharmaeuropa monograph. There is now a monograph for Agnus castus fruit in the Ph Eur (5th Edition) and all future batches of herbal substance will be tested to this monograph.

Satisfactory certificates of analysis for the herbal substance have been provided.

HERBAL PREPARATION

General information

Herbal preparation: chaste tree fruits dry extract

Scientific name of the plant: *Vitex agnus-castus* L.

Synonyms of the herbal substance: *Agnus-castus vulgaris* Carr., *Vitex verticillata* Lam., chaste tree, hemp tree, wild lavender, monk's pepper tree, keuschlamm or mönchspfeffer.

Parts of the plant used: dried fruits

Name of the herbal substance: chaste tree fruits (*Agni casti fructus*)

Ratio of the herbal substance to the herbal preparation (native): 7 - 13:1

Extraction solvent: ethanol 60 % (m/m)

The dry extract preparation is a pale brown, flowable powder with a characteristic aromatic odour and slightly bitter taste. It consists of 10 % native extract and 90 % liquid glucose (dry substance). The particle size of the dry extract is at least 80 % < 0.1 mm.

Manufacture

Description of Manufacturing Process and Process Controls

A satisfactory description of the manufacturing process and a flow diagram has been provided.

Control of Materials

Certificates of analysis for all materials used in the manufacture of the herbal preparation are provided. Excipients described in a pharmacopeia are tested and released according to their Ph. Eur. monograph. The excipient water is tested according to the manufacturer's monograph, which is satisfactory.

Controls of Critical Steps and Intermediates

There are no critical steps identified as the manufacture of the herbal preparation is considered to be a standard procedure.

Process Validation and/or Evaluation

The applicant has provided a satisfactory process validation report for batches of herbal preparation.

Control of Herbal Preparation

Specification

A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation

Analytical Procedures

Satisfactory analytical procedures are used to control the herbal preparation.

Validation of Analytical Procedures

All analytical procedures have been appropriately validated.

Batch Analyses

Certificates of analysis (CoA) have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

Justification of Specification

The proposed specification has been justified satisfactorily.

Container Closure System

Satisfactory specifications have been provided by the supplier, together with the declaration of compliance with Directive 90/128 EC, as amended. The primary packaging materials also comply with Directive 2002/72/EC, relating to foodstuffs.

Stability

Batches were packed in the final container closure system and stored under ICH real time, and accelerated conditions. The data support the proposed retest period of 24 months. Based on the results, no specific declaration of storage is applicable, although it is recommended that the dry extract is stored protected from light, heat and moisture. This is acceptable.

HERBAL PRODUCT

Description and Composition of the Herbal Product

Qualitative composition of the product

Component	Ref standard
Drug substance Dry extract of Chaste tree fruits (7 - 13:1) Extraction solvent: ethanol 60 % (m/m) *, **	
Other constituents Tablet core: Liquid glucose (dry substance) Silica, colloidal anhydrous Lactose monohydrate Magnesium stearate Maize starch Cellulose, microcrystalline Sodium starch glycolate (type A)	Ph Eur Ph Eur Ph Eur Ph Eur Ph Eur Ph Eur Ph Eur
Film coating: Lactose monohydrate Hydroxypropylmethylcellulose Macrogol 4000 Titanium dioxide E 171 Iron (III)-oxide E 172 (= red iron oxide)	Ph Eur Ph Eur Ph Eur Ph Eur HSE
Purified water*, **	

* The water used for the manufacture of the extraction solvent corresponds to the monograph,

** Not contained in the drug product.

Manufacture

Description of Manufacturing Process and Process Controls

Manufacture of the herbal product is by the standard direct tableting method. The components for the tablet mixture are weighed and sieved before being mixed homogenously in a mixing barrel. The mixed tablet mass is then pressed to form tablet cores on a rotary pelleting machine before being coated. The film-coated tablets are then sealed into mono blisters. The blisters are packaged into folding cartons and equipped with the package leaflet.

A satisfactory flow diagram outlining the various stages of the manufacturing process and the in-process controls is provided.

Control of Critical Steps and Intermediates

A number of in-process control tests are performed during the manufacturing process. All are considered adequate.

Process Validation and/or Evaluation

Process validation results show that the production process provides a reproducible product of satisfactory quality and consistency. All results were within the release specification.

Control of Excipients

All the excipients and analytical procedures are as specified by the pharmacopoeia monographs. The colouring agents, titanium dioxide E 171 and iron (III) oxide E 172, comply with Directive 2001/50/EC (amending Directive 95/45/EC) and, in the case of titanium dioxide, the Ph. Eur.monograph.

Certificates of analysis of the excipients have been provided by the suppliers. The only excipients not described in a pharmacopoeia are iron (III) oxide E 172 and water used in the manufacture of the herbal extract. The Certificates of analysis for the iron (III) oxide E 172 and water confirm that these excipients are of satisfactory quality.

Excipients of Human or Animal Origin

A satisfactory declaration has been provided by the supplier of lactose monohydrate that this excipient is sourced from healthy animals suitable for human consumption. The applicant confirms that the magnesium stearate used is of vegetable origin.

Control of Herbal Product

Specification

The finished product specifications at release and end of shelf life are detailed and the tests and limits used were found to be satisfactory for a product of this nature.

Analytical Procedures / Validation of Analytical Procedures

Satisfactory details have been provided on all analytical procedures and these analytical procedures are valid.

Batch Analyses

Certificates of Analysis have been presented for batches of the drug product demonstrating little inter-batch variation.

Characterisation of Impurities

No toxic degradation products are known to come from this herbal preparation.

Reference Standards or Materials

Certificates of Analysis for all the markers, including the reference substance, have been provided by the finished product manufacturer.

Container Closure System

The film-coated tablets are sealed into polypropylene mono blisters. Specifications have been provided by the suppliers. The components of the primary packaging system, including the sealing layer, comply with Directive 2002/72 relating to contact with foodstuffs.

Stability

Stability studies were conducted under ICH conditions (long-term and accelerated) on product batches in the container type proposed for marketing.

Based on the results a proposed shelf life of 3 years with no special storage conditions is justified.

PRODUCT LITERATURE

The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product is pharmaceutically satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are

able to act upon the information that it contains.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY

This product is satisfactory and a Traditional Herbal Registration can be granted.

NON-CLINICAL ASSESSMENT

NON CLINICAL ASPECTS

The Expert Safety Report submitted by the applicant lists relevant references to published work studying the toxicology of Agnus castus fruit.

NON CLINICAL OVERVIEW

The applicant has submitted a good literature review with this application. An Expert Report on Safety was provided which included reviews of some non-clinical data. The Expert Safety Report was written by a pharmacist with expertise in herbal medicines, and is dated 6 November 2008.

The overview submitted in support of this application is satisfactory.

Due to a shortage of published data on Agnus castus fruit, it is not possible to assess if the safety package for the phytochemical constituents of Agnus castus fruit is acceptable to the standards of today's GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and thus the lack of provision of a complete standard safety package may be acceptable and in compliance with guideline EMEA/HMPC/32116/05.

Data in the literature for genotoxic and carcinogenic potential of the product is still deficient as basic genotoxicity tests have not been conducted. The company have provided their assurance that they will address this lack of data before renewal of their licence.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC for this product is satisfactory.

ENVIRONMENTAL RISK ASSESSMENT

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION

The information supplied demonstrating traditional use of Agnus castus fruit is acceptable. An adequate literature review of Agnus castus fruit has been carried out by the applicant and no new non-clinical data was submitted for assessment with this application. Granting of a THR is acceptable.

CLINICAL ASSESSMENT

PROPOSED INDICATION

The applicant has submitted the following therapeutic indication:

“A traditional herbal medicinal product that has been used to help relieve the symptoms associated with premenstrual syndrome, based on traditional use only.”

It is to be noted that the recommended dose of the product under application is one tablet per day (each tablet contains 4mg of extract) containing the equivalent of 40mg of dried herb per tablet.

POSOLOGY AND METHOD OF ADMINISTRATION

The Applicant has submitted the following:

“For oral use only. For women experiencing premenstrual symptoms, take 1 tablet daily. Tablets should be taken at the same time of day if possible (morning or evening) and swallowed whole with plenty of liquid. Some individuals may need to take Kira Prem Film-coated tablets for up to 3 months for maximum benefit to occur. Women suffering from a current pituitary disorder should not take Kira Prem Film-coated tablets. Not for children and adolescents under 18 years.”

EFFICACY

No clinical efficacy data is required for registration of Traditional Herbal Medicinal Products (THMP).

EVIDENCE OF TRADITIONAL USE

Agnus castus fruit is generally accepted to have a tradition of use as an herbal medicine.

Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community.

Information has been provided in support of the medicinal use of Agnus castus fruit within the EU for a period exceeding 30 years.

The applicant has also provided a literature review demonstrating the use of Agnus castus fruit in Germany for more than 30 years. The indications listed included hypermenorrhoea, menstrual disorders due to corpus luteum insufficiency, premenstrual syndrome and deficient milk secretion.

The applicant has also provided information from a survey of 280 registered medical herbalists carried out in 1997 to estimate the traditional medicinal use of Agnus castus fruit. Ninety-four per cent of the 153 respondents indicated that they used the extracts to treat their patients for premenstrual symptoms. The preparations used included tincture, fluid extract, solid and

powdered extracts.

Assessor's Comments

There is sufficient evidence of traditional use of *Agnus castus* fruit for a period of at least 30 years, including evidence for the treatment of symptoms associated with premenstrual syndrome at the same dose. Therefore a traditional herbal registration can be granted for this indication.

SAFETY REVIEW

Article 16 c 1 (d) requires the applicant to provide a bibliography of the safety data together with an expert report.

A safety review has been provided, as well as an expert report written by a pharmacist with expertise in herbal medicines. His CV has been included.

The Clinical Review of Safety submitted in the dossier outlined adverse events from controlled and uncontrolled studies and spontaneous reports relevant to the safety *Agnus castus* fruit.

Assessor's Comments

The Safety Review is comprehensive and reveals the main safety issues associated with treatment with *Agnus castus* fruit; the adverse effects appear to be mild and self-limiting, and include gastrointestinal disturbances, acne, menstrual disorders, pruritis and rashes. There is a theoretical risk of an interaction with other medicinal products that contain hormones. As the herb may have an effect on pituitary function, the product should not be used by women with a previous history of pituitary disorders (such as prolactinoma).

SUMMARY OF PRODUCT CHARACTERISTICS

The SPC for this product is satisfactory.

PATIENT INFORMATION LEAFLET

The PIL for this product is satisfactory.

LABELLING

All labelling is satisfactory.

DISCUSSION

This is an application for registration under the Traditional Herbal Medicinal Products Directive. The data supplied by the Applicant are sufficient to demonstrate 30 years of traditional use within the European Community. A satisfactory review of the available safety data relating to *Agnus castus* fruit has been provided.

RECOMMENDATIONS

A Traditional Registration may be granted.

OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY

The quality data submitted with this application are satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY AND SAFETY

No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

The Applicant has provided a bibliographic review which shows ample evidence for the use of *Agnus castus* fruit within the EU for a period exceeding 30 years.

A satisfactory review of the safety data has been provided.

The SPC, PIL and labelling are satisfactory.

RISK ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified.

KIRA PREM FILM-COATED TABLETS

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STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration on 03 March 2009
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 09 March 2009
- 3 The application was determined on 07 October 2009

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Kira[®] Prem Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

4mg of extract (as dry extract) from Agnus Castus fruit (*Vitex agnus castus* L.) (7 –13:1) (equivalent to 28 - 52 mg of Agnus Castus).

Extraction Solvent: Ethanol 60% (m/m).

Excipients: One film-coated tablet contains 124 mg lactose monohydrate and 36 mg of liquid glucose.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

Salmon pink, round, convex curved and with a score mark on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used to help relieve the symptoms associated with premenstrual syndrome, based on traditional use only.

4.2 Posology and method of administration

For oral use only.

For women experiencing premenstrual symptoms, take 1 tablet daily.

Tablets should be taken at the same time of the day if possible (morning or evening) and swallowed whole with plenty of liquid. Do not chew the tablets.

Some individuals may need to take Kira[®] prem for up to 3 months for maximum benefit to occur.

Not for children and adolescents under 18 years.

Women suffering from a current pituitary disorder should not take the product.

4.3 Contraindications

Hypersensitivity to agnus castus fruit or any other ingredient of the product.

This product is not recommended for use in children and adolescents under 18 years.

4.4 Special warnings and precautions for use

Agnus Castus is thought to act on the pituitary-hypothalamic axis and therefore patients with a history of a pituitary disorder should consult a doctor before using this product.

This product contains glucose: One film-coated tablet contains max. 36 mg of glucose.

This product contains lactose: One film-coated tablet contains max. 124 mg of lactose.

Patient with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

There are no published data available on drug interactions with extracts of agnus castus. Animal experiments have shown that the drug has got a dopaminergic effect. Theoretically there could be a reduction in the effectiveness of dopamine-receptor antagonists and / or a potentiation of dopamine-receptor agonists.

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Therefore it should be avoided during pregnancy or lactation. Additionally because of the potential for the product to have hormone-like actions the product should also be avoided by women who are trying to become pregnant.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Mild and reversible, transient side-effects are associated with the use of agnus castus. Postmarketing surveillance studies suggest that the approximate incidence of adverse effects is between 1.9 – 5%. Most frequently these are:

Nausea

Stomach disturbances

Headache

Diarrhoea

Allergic skin reactions.

If any signs of an allergic reaction occur the product should be withdrawn.

4.9 Overdose

In the event of an overdose, patients are advised to contact a doctor, pharmacist or qualified healthcare professional. A small overdose (up to 8 tablets) is unlikely to cause any symptoms. In the event of a larger overdose (more than 8 tablets), advice should be sought from a doctor. Management of a larger overdose should be symptomatic and supportive in nature.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

No pharmacodynamic studies with Kira[®] prem have been conducted. The pharmacodynamic properties are unknown.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Liquid glucose (dry substance)
Silica, colloidal anhydrous
Lactose monohydrate
Magnesium stearate
Maize starch
Cellulose, microcrystalline
Sodium starch glycollate (type A)

Film-coating:
Hypromellose
Lactose monohydrate
Macrogol 4000
Titanium dioxide E 171
Iron(III)-oxide E172 (red iron oxide)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life is 3 years.

6.4 Special precautions for storage

This product does not require any special storage conditions.

6.5 Nature and contents of container

Original packages containing 30 film-coated tablets.

Kira[®] Prem Film-coated tablets are packed in white-opaque polypropylene blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Cassella-med GmbH & Co.KG
Gereonsmuehlengasse 1
50670 Cologne
Germany

8 MARKETING AUTHORISATION NUMBER(S)

THR 29860/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/10/2009

10 DATE OF REVISION OF THE TEXT

07/10/2009

PATIENT INFORMATION LEAFLET



a company of

KLOSTERFRAU
HEALTHCARE GROUP



Patient Information Leaflet

Kira® prem

film-coated tablets
Agnus Castus fruit dry extract 4 mg

Please read this leaflet carefully before you start taking these tablets. It contains some important information about Kira® prem.

Keep this leaflet with the tablets. You may want to read it again or show it to your doctor, pharmacist or healthcare practitioner.

What is in this leaflet

1. What this product is and what it is used for
2. Before you take this product
3. How to take this product
4. Side-effects
5. After taking this product
6. Product description

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1. What this product is and what it is used for
Kira® prem is a traditional herbal medicinal product containing Agnus Castus fruit. Each film-coated tablet of this product contains 4 mg of extract (as dry extract) from Agnus Castus fruit (*Vitex agnus castus* L.) (7-13:1) (equivalent to 28–52 mg of Agnus Castus). Extraction solvent: Ethanol 60 % v/v.

Kira® prem is a traditional herbal medicinal product used to help relieve the symptoms associated with premenstrual syndrome. This usage is based on traditional use only.

2. Before you take this product

Do not take this product if you:

- Are lactose-intolerant (react badly to lactose or milk)
- Are pregnant, trying to become pregnant or are breast feeding
- Are allergic to any of the ingredients (see section 6)
- Are suffering from a pituitary disorder
- Are under 18 years of age

Tell your doctor before taking this product if you have:

- An intolerance to some sugars (see section 6)
- Had a pituitary disorder in the past

If you are taking dopamine-receptor antagonists or agonist-type drugs, there is a theoretical risk that this product may affect the way they work.

3. How to take this product

For women experiencing premenstrual symptoms, take 1 tablet daily. Tablets should be taken at the

same time of day if possible (morning or evening). Swallow the tablet whole with plenty of water or other liquid. Do not chew the tablets.

You can take the tablets with or without food. The maximum beneficial effect of this product may take up to 3 months to occur in some women.

Do not exceed the stated dose.

Do not give Kira® prem to children or adolescents under 18 years of age.

If you take too much of this product (overdose) if you take more than the recommended dose, speak to a doctor, pharmacist or healthcare practitioner and take this leaflet with you.

A small overdose (up to 8 tablets) may not cause any symptoms. In the event of a larger overdose (more than 8 tablets) advice should be sought from a doctor.

If you forget to take this product

Continue to take your usual dose at the usual time, it does not matter if you have missed a dose.

If you have any questions, or are unsure about anything, please ask your doctor, pharmacist or healthcare practitioner.

4. Side-effects

Like all medicines, this product can have side-effects. Any side-effects associated with Kira® prem are usually mild and disappear in a few days. Side-effects that have been reported are listed below.

- Nausea or feeling sick
- Indigestion

1

2

3

- Digestive upsets such as wind, bloating or diarrhoea
- Headache

If these persist for more than a few days, or become troublesome, stop taking this product. These common side-effects are often only temporary.

- Allergic skin reactions such as nettle rash, itching of the skin

Stop taking this product immediately if you experience any allergic skin reactions.

Other side-effects

Tell your doctor or pharmacist if you notice any other side-effect.

5. After taking this product

Do not use your tablets after the expiry date. Return any out-of-date tablets to your pharmacist who will dispose of them for you. The expiry date is printed on the box and the blister pack.

This medicine does not require any special storage conditions.

Keep your tablets out of the reach and sight of children.

Keep your tablets in the blister pack until it is time to take them.

6. Product description

Each film-coated tablet contains 4 mg of extract (as dry extract) from Agnus Castus fruit (*Vitex agnus castus* L.) (7-13:1) (equivalent to 28-52 mg of Agnus Castus). Extraction solvent: Ethanol 60 % v/v.

This product also contains the following ingredients:

Tablet core:

Liquid glucose, lactose monohydrate, silica colloidal anhydrous, magnesium stearate, maize starch, cellulose microcrystalline, sodium starch glycolate (type A)

Film-coating:

Lactose monohydrate, Hypromellose, macrogol 4000, titanium dioxide (E171), iron (III)-oxide (E172).

If you think you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. Each film-coated tablet contains 124 mg of lactose and 36 mg of liquid glucose.

Each pack contains 30 film-coated tablets.

Registration holder for this product

Cassella-med GmbH & Co.KG
Gereonsmuehlengasse 1
50670 Cologne
Germany

Manufacturer of this product

Klosterfrau Berlin GmbH
Motzener Strasse 41
12277 Berlin
Germany

Traditional herbal registration number:
THR 29860/0003

If you would like further information about this product, please contact:
Ceuta Healthcare Ltd.,
41 Richmond Hill,
BOURNEMOUTH BH2 6HS,
United Kingdom.

Telephone: 01202 780558
Fax: 01202 780559
Email: info@ceutahealthcare.co.uk

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For a large print, Braille or audio version of this leaflet, call Ceuta Healthcare Ltd.

Cassella-med GmbH is a company of the



LABELLING

