

PATIENT INFORMATION LEAFLET: SFERA AGNUS CASTUS

SCHEDULING STATUS **SO**

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

SFERA AGNUS CASTUS. Each capsule contains 400 mg *Vitex agnus-castus*

(Chaste tree) [berry, 4:1 extract].

Suitable for vegetarians and vegans.

No added sugar.

COMPLEMENTARY MEDICINE: WESTERN HERBAL MEDICINE

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you SFERA AGNUS CASTUS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SFERA AGNUS CASTUS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SFERA AGNUS CASTUS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What SFERA AGNUS CASTUS is and what it is used for
2. What you need to know before you use SFERA AGNUS CASTUS
3. How to use SFERA AGNUS CASTUS
4. Possible side effects
5. How to store SFERA AGNUS CASTUS
6. Contents of the pack and other information

1. WHAT SFERA AGNUS CASTUS IS AND WHAT IT IS USED FOR

SFERA AGNUS CASTUS is a Western Herbal Medicine which is used to help relieve symptoms associated with menopause, such as hot flushes.

SFERA AGNUS CASTUS is used (as a hormone normaliser) to help stabilise menstrual cycle irregularities and relieve premenstrual symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SFERA AGNUS CASTUS

Do not take SFERA AGNUS CASTUS:

- if you are hypersensitive (allergic) to any of the ingredients of SFERA AGNUS CASTUS (see section 6).
- if you are pregnant, or think you may be pregnant, or breastfeeding.

Warnings and precautions:

Consult your doctor prior to use, especially if you have a medical condition or are taking prescription medication.

Take special care with SFERA AGNUS CASTUS:

- if you are taking hormone-containing medications such as progesterone preparations, oral contraceptives or hormone replacement therapy. Consult a health care provider or doctor prior to use.

Children and adolescents

Children and adolescents under the age of 18 years should not take SFERA AGNUS CASTUS.

Other medicines and SFERA AGNUS CASTUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Consult a health care provider prior to use if you are taking hormone-containing medications such as progesterone preparations, oral contraceptives or hormone replacement therapy.

SFERA AGNUS CASTUS with food and drink:

Take SFERA AGNUS CASTUS before or after a meal with water.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery:

It is not always possible to predict to what extent SFERA AGNUS CASTUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SFERA AGNUS CASTUS affects them.

3. HOW TO TAKE SFERA AGNUS CASTUS

Do not share medicines you are taking with any other person.

Always take SFERA AGNUS CASTUS exactly as described in this leaflet or as your doctor, pharmacist or health care provider told you. Check with your doctor, pharmacist or health care provider if you are not sure.

Adult women: Take one (1) capsule orally daily in the morning with food or as directed by your healthcare provider. Use for at least 3 months to see beneficial effects.

If you take more SFERA AGNUS CASTUS than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of SFERA AGNUS CASTUS:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

SFERA AGNUS CASTUS can have side effects. Not all side effect reported for SFERA AGNUS CASTUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SFERA AGNUS CASTUS, please consult your health care provider for advice. If any of the following happens, stop taking SFERA AGNUS CASTUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SFERA AGNUS CASTUS. You may need urgent medical attention or hospitalisation. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to pharmacist@sfera-nutrition.co.za or to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of SFERA AGNUS CASTUS.

5. HOW TO STORE SFERA AGNUS CASTUS.

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from moisture.
- Keep the container well closed.
- Keep in the original container until ready for use.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SFERA AGNUS CASTUS contains

- The active substances are: Each capsule contains 400 mg *Vitex agnus-castus* (Chaste tree) [berry, 4:1 extract].
- The other ingredient is: A Vegetarian capsule, natural flow agent and microcrystalline cellulose.

What SFERA AGNUS CASTUS looks like and contents of the pack

SFERA AGNUS CASTUS capsules are clear size "0" capsules filled with a brown powder. SFERA AGNUS CASTUS: 60 capsules are packed into an amber glass bottle, with a golden plastic lid with plastic seal liner, desiccant sachet and outer protective tamperproof shrink sleeve on the cap.

Holder of Certificate of Registration

Sfera Bio Nutrition (Pty) Ltd.
5 Regency Drive, Block C, Route 21 Corporate Park, Pretoria, 0181
Telephone: 012 751 7117 | Website: www.sfera-nutrition.co.za

This leaflet was last revised in

January 2024.

Access to the corresponding Professional Information

Detailed information on this medicinal product is available from pharmacist@sfera-nutrition.co.za or www.sfera-nutrition.co.za

PASIËNT INLIGTINGSBLAD: SFERA AGNUS CASTUS

SKEDULERING STATUS S0

PRODUKNAAM, STERKE EN DOSEERVORM

SFERA AGNUS CASTUS. Elke kapsule bevat: 400 mg *Vitex agnus-castus* (Kuisboom) [bessie,4:1 ekstrak].

Geen suiker bygevoeg.

Geskiik vir vegetariërs en vegane.

KOMPLEMENTÊRE MEDISYNE: WESTERSE KRUIE MEDISYNE

Hierdie ongeregistreerde medisyne is nog nie geëvalueer deur die SAHPRA vir die kwaliteit, veiligheid of vir die voorgename gebruik nie.

Lees die hele blaadjie noukeurig deur omdat dit belangrike inligting vir u bevat.

SFERA AGNUS CASTUS is beskikbaar sonder 'n dokter se voorskrif, vir u om te gebruik om 'n minder ernstige siekte te behandel. Nogtans behoort u **SFERA AGNUS CASTUS** word versigtigheid te gebruik om die beste resultate daaruit te verkry.

- Hou hierdie blaadjie. U mag dit weer wil lees.
- Moenie **SFERA AGNUS CASTUS** deel met enige ander persoon nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat is in hierdie blaadjie

1. Wat is **SFERA AGNUS CASTUS** en waarvoor word dit gebruik
2. Wat u moet weet voordat u **SFERA AGNUS CASTUS** gebruik
3. Hoe om **SFERA AGNUS CASTUS** te gebruik
4. Moontlike nuwe-effekte
5. Hoe om **SFERA AGNUS CASTUS** te berg
6. Inhoud van die verpakking en ander inligting.

1. WAT IS SFERA AGNUS CASTUS EN WAARVOOR WORD DIT GEBRUIK

SFERA AGNUS CASTUS is 'n Westerse Kruië Medisyne wat gebruik word om die simptome wat met menopouse verband hou, soos warm gloede te verlig. **SFERA AGNUS CASTUS** word gebruik as hormoon normaliseerder om onreëlmatighede in die menstruele siklus te stabiliseer en premenstruele simptome te verlig.

2. WAT U MOET WET VOORDAT U SFERA AGNUS CASTUS GEBRUIK

Moenie **SFERA AGNUS CASTUS** neem nie:

- indien u hipersensitief (allergies) is vir enige van die bestanddele van **SFERA AGNUS CASTUS** (sien afdeling 6).
- indien u swanger is, of dink dat u swanger is, of borsvoed

Waarskuings en voorsorgmaatreëls:

Raadpleeg 'n gesondheidsorgverskaffer as die simptome voortduur of vererger. Raadpleeg u dokter voordat u **SFERA AGNUS CASTUS** begin gebruik, veral as u 'n mediese toestand het of voorskifmedisyne gebruik.

Neem spesiale sorg met SFERA AGNUS CASTUS:

- indien u medikasie neem wat hormone bevat, soos progesteron preparate, orale voorbehoedmiddels of hormoonvervangings terapie. Raadpleeg 'n gesondheidsorgverskaffer of dokter voordat u **SFERA AGNUS CASTUS** begin gebruik.

Kinders en adolessente

Kinders en adolessente onder die ouderdom van 18 jaar moet nie **SFERA AGNUS CASTUS** neem nie.

Ander medisyne en SFERA AGNUS CASTUS

Vertel altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in.)

Raadpleeg 'n gesondheidsorgverskaffer voordat **SFERA AGNUS CASTUS** begin gebruik word as u hormoon-bevattende medisyne gebruik, soos progesteron-preparate, orale voorbehoedmiddels of hormoonvervangings terapie.

SFERA AGNUS CASTUS saam met voedsel en vloeistowwe:

Neem **SFERA AGNUS CASTUS** voor of na 'n maaltyd met water.

Swangerskap en borsvoeding:

Indien u swanger is of borsvoed, dink dat u swanger is of van plan is om swanger te raak, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer voordat u hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie:

Dit is nie altyd moontlik om te voorspel in watter mate **SFERA AGNUS CASTUS** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet toesien dat hulle nie aan bogenoemde aktiwiteite deelneem nie totdat hulle bewus is van die mate waarin **SFERA AGNUS CASTUS** hulle beïnvloed.

3. HOE OM SFERA AGNUS CASTUS TE GEBRUIK

Moenie medisyne wat u neem met enige ander persoon deel nie. Neem altyd **SFERA AGNUS CASTUS** presies soos voorgeskryf in hierdie pamflet of soos u dokter, apteker of gesondheidsorgverskaffer vir u gesê het. Raadpleeg u dokter, apteker of gesondheidsorgverskaffer as u nie seker is nie.

Volwasse vroue: Neem een (1) kapsule daagliks oraal in die oggend saam met voedsel, of soos aangedui deur u gesondheidsorgverskaffer. Gebruik minstens 3 maande om voordelige effekte te sien.

Indien u meer SFERA AGNUS CASTUS neem as wat u behoort te neem:

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, vra hulp by die naaste hospitaal of gif hulp sentrum.

Indien u vergeet om 'n dosis SFERA AGNUS CASTUS te neem:

Moenie 'n dubbele dosis neem om die vergete enkel dosis in te haal nie.

4. MOONTLIKE NEWE EFFEKTE

SFERA AGNUS CASTUS kan nuwe effekte hê. Nie al die nuwe effekte aangemeld vir **SFERA AGNUS CASTUS** is ingesluit in hierdie blaadjie nie.. Raadpleeg u gesondheidsorgverskaffer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar wanneer u **SFERA AGNUS CASTUS** neem. As enige van die volgende gebeur, moet u ophou om **SFERA AGNUS CASTUS** te neem en u dokter onmiddellik inlig of na die ongevalle-afdeling in u naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak,
- Uitslag of jeuk,
- Floute ervaar

Dit is alles baie ernstige nuwe-effekte. As u dit het, kan u 'n ernstige reaksie op **SFERA AGNUS CASTUS** hê. U mag dringende mediese hulp of hospitalisasie benodig. Stel u dokter of apteker in kennis as u nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie.

Rapporteer van nuwe-effekte

As u nuwe-effekte kry, moet u met u dokter of apteker praat. U kan ook nuwe-effekte aan pharmacist@sfera-nutrition.co.za of aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", aalyn onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **SFERA AGNUS CASTUS** te voorsien.

5. HOE OM SFERA AGNUS CASTUS TE BERG

- Hou alle medisyne buite bereik van kinders.
- Berg by of benede 25 °C.
- Beskerm teen vog.
- Hou die houer goed toe.
- Berg in die oorspronklike houer totdat gereed is vir gebruik.
- Moenie in 'n badkamer berg nie.
- Moenie gebruik na die vervaldatum soos op die bottel aangedui nie.
- Moenie alle ongebruikte medisyne terug na u apteker toe.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat SFERA AGNUS CASTUS bevat

- Die aktiewe bestanddele is: Elke kapsule bevat: 400 mg *Vitex agnus-castus* (Kuisboom) [bessie,4:1 ekstrak].
- Die ander bestanddeel is: 'n Vegetariese kapsule, natuurlike vloeimiddel en mikrokristallyne sellulose.

Hoe SFERA AGNUS CASTUS lyk en die inhoud van die verpakking

SFERA AGNUS CASTUS kapsules is deursigtige grootte "0" kapsules gevul met 'n bruin poeier. **SFERA AGNUS CASTUS**: 60 kapsules word verpak in 'n amberkleurige glasbottel, met 'n goue deksel met 'n druk-seël voering, droogmiddelsakkie en 'n beskermende krimp-omhulsel om die deksel.

Houer van Registrasiesertifikaat

Sfera Bio Nutrition (Pty) Ltd.
5 Regency Rylaan, Block C, Route 21 Corporate Park, Pretoria, 0181
Telefoon: 012 751 7117 | Webwerf: www.sfera-nutrition.co.za

Hierdie pamflet is laas hersien in

Januarie 2024.

Registrasie nommer

Sal gealokteer word deur SAHPRA tydens registrasie.

Toegang tot die ooreenstemmende professionele inligting

Gedetailleerde inligting oor hierdie medisyne is beskikbaar by pharmacist@sfera-nutrition.co.za of www.sfera-nutrition.co.za