MENOSOOTHE Professional Information

Complementary Medicine: Discipline Specific

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

SCHEDULING STATUS

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1. NAME OF MEDICINE

Menosoothe, capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Glycine max (Soybean) seed extract (standardised to 40% isoflavones)	43,75 mg
Actaea racemosa (Black Cohosh) root extract standardised to 2,5% triterpene glycosides)	80,00 mg
Angelica sinensis (Dong Quai) root extract standardised to 1% ligustilide	50,00 mg

Sugar free.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsules.

Size 0 vegetable capsules filled with brown powder.

4. CLINICAL PARTICULARS

4. 1 Therapeutic indications

Menosoothe is a Western Herbal Medicine used to assist in the relief of menopausal symptoms, including hot flushes, night sweats, mood disturbances and sleep disturbances.

4. 2 Posology and method of administration

Posology

Adults (18 years and older): 1 capsule twice daily after meals

Method of administration

For oral use.

4. 3 Contraindications

- Hypersensitivity to the active ingredients in **Menosoothe** or to any of the excipients listed in section 6.1.
- Not to be taken during pregnancy and breastfeeding.

4. 4 Special warnings and precautions for use

Menosoothe should be used with care in:

- Consult your health care provider prior to use if taking medication or if a medical condition is present
- Individuals with hormone-sensitive conditions
- Individuals with liver and kidney problems, heavy alcohol users. Patient should stop using **Menosoothe** if they develop symptoms suggestive of liver problems such as

tiredness, loss of appetite, yellowing of skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine.

4. 5 Interactions with other medicines and other forms of interactions

Menosoothe may have interactions with the following medicines:

- Anticoagulants/antiplatelets – May increase bleeding risk

4. 6 Fertility, pregnancy and lactation

The use during pregnancy and lactation is not recommended.

No fertility data available.

4. 7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain **Mencocalm** does not adversely affect their performance.

4. 8 Undesirable effects

Menosoothe are generally well-tolerated, but can have side effects:

System Organ Class	**Frequency Unknown**
Gastrointestinal disorders	Gastrointestinal irritation,
Central Nervous system disorders	Headache
Skin and subcutaneous tissue disorders	Hypersensitivity reactions, photosensitivity

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4. 9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8)

Treatment of overdose is symptomatic and supportive

5. PHARMALOGICAL PROPERTIES

5. 1 Pharmacodynamic properties:

Pharmacological Classification: Category D: Complimentary Medicine: Discipline Specific

Pharmacotherapeutic group and ATC Code: D33.6 – Western Herbal Medicine

5. 2 Pharmacokinetic properties:

No pharmacokinetic studies have been performed on **Menosoothe** as a combination product.

6. PHARMACEUTICAL PARTICULARS

6. 1 List of excipients

Magnesium stearate, Maize starch, Microcrystalline Cellulose, silicon dioxide

6. 2 Incompatibilities

Not applicable

6. 3 Shelf life

24 months

6. 4 Special precautions for storage

- Store at or below 30 ˚C.
- Protect from light and moisture.
- Do not use after the expiry date stated on the carton.
- Store in the original package.

6. 5 Nature and contents of the container

Size 0 white vegetable capsules filled with brown powder,

packed into blisters (10 capsules per blister) and packed in to a carton containing 60 capsules

6. 6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirement.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Crux Pharmaceuticals (Pty) Ltd

630 Jacqueline Drive

Garsfontein

Pretoria

0042

Marketed by:

Nature Life CC Trading as Naturelife SA

Unit 2, Blue, WOW Business Park,

Ballito

KZN

4390

8. REGISTRATION NUMBER(S):

To be allocated

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT

April 2026