

PROFESSIONAL INFORMATIONScheduling status: S0

D33.6 Western Herbal, Complementary Medicine: Discipline Specific.

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

1. NAME OF THE MEDICINE**GNC HORNY GOAT WEED CAPSULES****2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsules contains:

Epimedium sagittatum (Horny Goat Weed, leaf extract)	300 mg
Maca Root Extract	125 mg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules

Clear gelatine capsules filled with light-brown powder.

4. CLINICAL PARTICULARS**4.1. Therapeutic indications**

HORNY GOAT WEED CAPSULES contain Western Herbs traditionally used to support or improve sexual health.

4.2. Posology and method of administrationPosology*Adults:*

The usual dose is two (2) capsules daily or as prescribed. Do not exceed the recommended dosage.
Do not give HORNY GOAT WEED CAPSULES to children under 18 years.

Method of administration

This medicine is taken orally.

4.3. Contraindications

- Known hypersensitivity to any of the ingredients in HORNY GOAT WEED CAPSULES.
- Pregnancy and lactation
- Avoid use in patients with a hormone sensitive condition.

4.4. Special warnings and precautions for use

Take special care in patients who have:

- heart problems
- a bleeding disorder or are taking blood thinning medications. Horny goat weed might slow blood clotting and increase the risk of bleeding
- high blood pressure, a hormone-sensitive condition or thyroid problems. HORNY GOAT WEED CAPSULES contains Maca Root which may affect these conditions.

4.5. Interaction with other medicines and other forms of interaction

- Anticoagulant/antiplatelet medicine: Horny goat weed might increase the risk of bleeding.
- Oestrogens: Horny goat weed and Maca might potentiate the therapeutic and adverse effects of oestrogens
- Antihypertensive medicine: Horny goat weed and Maca may increase the risk of hypotension when taken with antihypertensive medicine

4.6. Fertility, pregnancy and lactation

Avoid use. The safety of HORNY GOAT WEED CAPSULES in pregnancy and lactation has not yet been established.

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Tabulated summary of adverse reactions:

System Organ Class	
Nervous system disorders	
<i>Frequency unknown:</i>	Dizziness
Gastrointestinal disorders	
<i>Frequency unknown:</i>	Vomiting, Dry mouth and thirst
Respiratory, thoracic and mediastinal disorders	
<i>Frequency unknown:</i>	Breathing problems
Blood and lymphatic system disorders	
<i>Less frequent</i>	Bleeding complications
Immune system disorders	
<i>Frequency unknown:</i>	Hypersensitivity reaction

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. Healthcare providers are asked to report any suspected adverse reactions 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>

4.9. Overdose

In overdose, side effects as indicated in Section 4.8, can be precipitated and/or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Preliminary studies have suggested that Horny goat weed may act as a natural alternative to drugs for erectile dysfunction (ED). Epimedium, the suspected active component of horny goat weed, appears to increase blood flow and improve sexual function, or act as a phosphodiesterase inhibitor, similar to some drugs used for ED. Horny goat weed also contains phytoestrogens, chemicals that may exhibit characteristics of the hormone oestrogen.

5.2. Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on HORNY GOAT WEED CAPSULES.

5.3. Preclinical safety data

There are no other known preclinical safety data of relevance to the prescriber which are additional to that already included in other sections.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Gelatine capsules, magnesium stearate, microcrystalline cellulose and silicon dioxide

6.2. Incompatibilities

Not applicable

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 25°C, in a dry place in the original container

6.5. Nature and contents of container

HDPE container with a flip top lid, a foam insert and a silica gel desiccant. The container is sealed with a heat induction safety seal. Pack size of 60 capsules.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

GNC South Africa (Pty) Ltd, Central office park No.4, 257 Jean Avenue, Centurion, 0157.

8. REGISTRATION NUMBER(S)

To be allocated by SAHPRA upon registration

9. DATE OF FIRST AUTHORISATION

To be allocated by SAHPRA upon registration.

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