

PROFESSIONAL INFORMATION

Complementary Medicine

D 33.7 Combination Product

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

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

DAMAC™ Softgel Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Softgel Capsule contains:	
<i>Eleutherococcus senticosus</i> (Siberian Ginseng)	150 mg
<i>Epimedium</i> (Horny Goat Weed)	300 mg
<i>Lepidium meyenii</i> (Maca)	20 mg
<i>Rehmannia</i> (Chinese foxglove)	20 mg
Zinc	* 5,5 mg

*50 % of Recommended daily dietary allowance

Sugar free.

For a full list of excipients, see section 6.1

DAMAC is Halaal certified with the NIHT (National Independent Halaal Trust)

3 PHARMACEUTICAL FORM

Softgel capsules.

Dark green, oblong, softgel capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Enhances libido, sexual desire and performance in men.

4.2 Posology and method of administration

Posology

One capsule to be taken twice daily with a meal, or as directed by a healthcare professional.

Method of administration

For oral use.

4.3 Contraindications

The use of DAMAC is contraindicated in:

- Hypersensitivity to any of the ingredients contained in DAMAC (see section 6.1).
- Individuals with cardiovascular disorders.
- Individuals with hypertension.
- Individuals with diabetes.
- Women.

4.4 Special warnings and precautions for use

- DAMAC is not suitable for diabetics as it can affect blood sugar levels, either lowering or increasing blood sugar levels (see section 4.3).
- DAMAC is not suitable for use by vegetarians.

4.5 Interaction with other medicines and other forms of interaction

Medicines for diabetes (Anti-diabetic medicines)

DAMAC may affect blood sugar levels. Concomitant use of DAMAC with medicines for diabetes may cause an increase or decrease in blood sugar levels, making the anti-diabetic medication less effective (see section 4.3).

Medicines that slow blood clotting (Anticoagulants and NSAIDs)

DAMAC may slow blood clotting. The use of DAMAC with anticoagulants (clopidogrel, enoxaparin, heparin, warfarin etc.) and NSAIDs (diclofenac, ibuprofen) may increase the chances of bruising and bleeding.

4.6 Fertility, pregnancy and lactation

DAMAC is not indicated for use in women.

DAMAN is contra-indicated in pregnant and lactating women (see section 4.3).

4.7 Effects on ability to drive and use machines

DAMAC can cause drowsiness. You should be aware of how you react to DAMAC before you drive or use machinery.

4.8 Undesirable effects

The following side-effects have been reported:

<i>Eleutherococcus senticosus</i> (Siberian Ginseng)	Nausea, diarrhoea, insomnia, drowsiness, confusion, nervousness, anxiety, headache, fever, arrhythmia (incl. tachycardia), hypertension, rash and muscle spasm.
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<i>Epimedium</i> (Horny Goat Weed)	Nausea, vomiting, dry mouth, thirst, tachyarrhythmia (disturbance in the regular rhythm of the heartbeat), fever, hypomania. Horny goat weed may also dilate coronary vessels and lower blood pressure. Long-term use may cause aggressiveness, irritability, or respiratory arrest.
<i>Lepidium meyenii</i> (Maca)	None known.
<i>Rehmannia</i> (Chinese foxglove)	Diarrhoea, abdominal pain, oedema, fatigue, vertigo and heart palpitations.
Zinc	Nausea, vomiting, loss of appetite, abdominal cramps, diarrhoea and headache.

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 “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

4.9 Overdose

The treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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***Eleutherococcus senticosus* (Siberian Ginseng)** helps to enhance physical, sexual and mental performance, whilst increasing energy and resistance to the harmful effects of stress.

***Epimedium* (Horny Goat Weed)** is a natural phyto-aphrodisiac that supports libido. It is used to arouse sexual desire and enhance sexual performance.

***Lepidium meyenii* (Maca)** enhances sexual desire in men and is used for its aphrodisiac properties. It has an energising effect – increasing energy, stamina and endurance as well as increasing mental clarity.

***Rehmannia* (Chinese foxglove)** acts as a general tonic.

Zinc is an essential trace mineral which plays an important role in reproductive health.

5.2 Pharmacokinetic properties

No information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin wet solution

Purified water

Sodium copper chlorophyllin

Sunflower oil

Titanium dioxide (E171)

Wax mixture

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C in the original container. Keep well closed.

Keep out of reach of children.

6.5 Nature and contents of container

Soft-Gel Capsules in white HDPE plastic containers of 30's and 60's.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Vikeleka Herbal Pharmaceuticals CC

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8 REGISTRATION NUMBER

To be allocated

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of publication: October 2020

10 DATE OF REVISION OF THE TEXT

January 2021

Scroll down for Damac Professional Information (Afrikaans Version)

PROFESSIONELE INLIGTING

Komplementêre medisyne

D 33.7 Kombinasie Produk

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer in terme van kwaliteit, veiligheid of die beoogde gebruik nie.

SKEDULERINGSSTATUS

S0

1 NAAM VAN DIE MEDISYNE

DAMAC™ Sagtejelkapsules

2 KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Elke sagtejelkapsule bevat:	
<i>Eleutherococcus senticosus</i> (Siberiese ginseng)	150 mg
<i>Epimedium</i> (Horny Goat Weed)	300 mg
<i>Lepidium meyenii</i> (Maka)	20 mg
<i>Rehmannia</i> (Chinese vingerhoedplant)	20 mg
Sink	*5,5 mg

*50% van die aanbevole daaglikse dieet toelaag

Suiker vry.

Vir 'n volledige lys van onaktiewe stowwe, sien afdeling 6.1

DAMAC is Halaal gesertifiseer deur NIHT(National Independent Halaal Trust)

3 FARMASEUTIESE VORM

Sagtejelkapsule.

Donkergroen, langwerpige, sagtejelkapsules.

4 KLINIESE BESONDERHEDE

4.1 Terapeutiese indikasies

Verhoog libido, seksdrang en seksuele prestasie by mans.

4.2 Posologie en metode van toediening

Posologie

Neem een kapsule twee keer per dag saam met 'n maaltyd, of soos deur 'n professionele gesondheidsdeskundige aangedui.

Metode van toediening

Vir orale gebruik.

4.3 Kontraindikasies

Die gebruik van DAMAC word teenaangedui in die volgende gevalle:

- Hipersensitiwiteit vir enige van die bestanddele wat in die produk voorkom (sien afdeling 6.1).
- Individue met kardiovaskulêre versteurings.
- Individue met hoë bloeddruk.
- Individue met suiker siekte.
- Vrouens.

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik

- DAMAC is nie geskik vir diabetese nie omdat dit die bloedsuikervlakke kan beïnvloed deur bloedsuikervlakke óf te verlaag óf te verhoog (sien afdeling 4.3).
- DAMAC is nie geskik vir vegetariërs nie.

4.5 Interaksie met ander medisyne en ander vorms van interaksie

Medisyne vir diabetes (Antidiabetiese medisyne)

DAMAC kan bloedsuikervlakke beïnvloed. Meegaande gebruik van DAMAC met medisyne vir suiker siekte kan 'n toename of afname in bloedsuikervlakke veroorsaak, wat die antidiabetiese medikasie minder doeltreffend maak (sien afdeling 4.3).

Medisyne wat bloedstolling vertraag (Antistolmiddels en NSAïMs)

DAMAC kan bloedstolling vertraag. Die gebruik van DAMAC tesame met antistolmiddels (klopidogrel, enoksaparien, heparien, warfarien ens.) en NSAïMs (diklofenak, ibuprofeen) kan die moontlikheid van kneusing en bloeding verhoog.

4.6 Fertiliteit, swangerskap en laktasie

DAMAC word nie vir gebruik deur vrouens aangedui nie.

DAMAC is teenaangedui vir swanger en borsvoedende vroue (sien afdeling 4.3).

4.7 Effekte op die vermoë om te bestuur en die gebruik van masjinerie

DAMAC kan lomerigheid veroorsaak. Jy moet seker maak dat jy nie betrokke raak in die bogenoemde aktiwiteite totdat jy bewus is tot en met watter mate DAMAC jou affekteer nie.

4.8 Ongewenste effekte

Die volgende nuwe-effekte is aangemeld

<i>Eleutherococcus senticosus</i> (Siberiese ginseng)	Naarheid, diarree, slaaploosheid, duiseligheid, verwarring, senuagtigheid, angstigheid, hoofpyn, koors, aritmie (insl. hartversnelling), hoë bloeddruk/hipertensie, uitslag en spierspasma.
<i>Epimedium</i>	Naarheid, vomering, droë mond, dorstigheit, tagi-aritmie (versteuring van die normale ritme van

(Horny Goat Weed)	die hartklop), koors, hipomanie. Epimedium kan ook bloedvate verwyd en bloeddruk verlaag. Langtermyngebruik kan lei tot aggressie, geïrriteerdheid, of asemhalingstilstand.
<i>Lepidium meyenii</i> (Maka)	Geen sover bekend nie.
<i>Rehmannia</i> (Chinese vingerhoedplant)	Diarree, buikpyn, edeem, uitputting, duiseligheid en hartkloppings.
Sink	Naarheid, vomering, verlies van eetlus, maagkrampe, diarree en hoofpyn.

Aanmelding van vermoedelike ongewenste reaksies

Aanmelding van vermoedelike ongewenste reaksies na goedkeuring van die medisyne is belangrik. Dit laat volgehoue monitering van die voordeel/risiko balans van die medisyne toe. Gesondheidsorgwerkers word versoek om enige vermoedeilike ongewenste reaksies by SAHPRA aan te meld via die “**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**”, wat aanlyn gevind kan word onder SAHPRA se publikasies:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

4.9 Oordosering

Die behandeling van oordosering is simptomaties en ondersteunend.

5 FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

Komplementêre medisyne

Kombinasie Produk

D 33.7

***Eleutherococcus senticosus* (Siberiese ginseng)** help om liggaamlike, seksuele en verstandelike prestasie te verhoog, terwyl energie en weerstand teen die skadelike uitwerking van stres verhoog word.

***Epimedium* (Horny Goat Weed)** is 'n natuurlike plantaardige seksstimuleermiddel wat libido (geslagsdrif) ondersteun. Dit word gebruik om die seksdrang aan te wakker en verhoog seksuele prestasie.

***Lepidium meyenii* (Maka)** verbeter die seksdrang in mans en word vir die seksstimulerende eienskappe daarvan gebruik. Dit het 'n energiewekkende uitwerking – verhoogde energie, stamina en uithou vermoë asook verbeterde helderheid van die verstand.

***Rehmannia* (Chinese vingerhoedplant)** funksioneer as 'n generiese tonikum.

Sink is 'n noodsaaklike spoormineraal wat 'n belangrike rol in reprodktiewe gesondheid speel.

5.2 Farmakokinetiese eienskappe

Geen inligting is beskikbaar nie.

6 FARMASEUTIESE EIENSKAPPE

6.1 Lys van onaktiewe bestanddele

Gelatien in vogtige oplossing,

Natriumkoperchlorofillien

Sonneblomolie

Titaandioksied (E171)

Wasmengsel

Water, gesuiwer

DAMAC is Halaal gesertifiseerd deur NIHT(National Independent Halaal Trust)

6.2 Onverenigbaarhede

Nie van toepassing nie.

6.3 Rakleef tyd

24 maande.

6.4 Spesiale voorsorgmaatreëls vir berging

Bewaar by of benede 25 °C in die oorspronklike houer. Hou dig toe.

Hou buite bereik van kinders.

6.5 Aard en inhoud van houer

Sagtejelkapsules in wit HDPE plastiekhouders van 30's en 60's.

6.6 Spesiale voorsorgmaatreëls vir vernietiging en ander hantering

Geen spesiale voorsorgmaatreëls vir vernietiging is nodig nie.

7 HOUER VAN REGISTRASIESERTIFIKAAT

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8 REGISTRASIENOMMER

Sal toegeken word

9 DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN DIE GOEDKEURING

Datum van publikasie: Oktober 2020

10 DATUM VAN HERSIENING VAN DIE TEKS

Januarie 2021