PROFESSIONAL INFORMATION

Category D: human complementary medicine. This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Swissgarde Stressgarde Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per capsule: Ashwagandha Root (Withania Somnifera) 350,0mg, Magnesium Sulphate 160 mg providing Elemental Magnesium 15,75 mg, Vitamin B6 (pyridoxine) 1,3mg, Vitamin B12 (Cyanocobalamin) 3,0 mcg, Vitamin D3 Cholecalciferol) 300 IU, Zinc Oxide 8 mg providing Elemental Zinc 6,4 mg, Fucoidan 10,0 mg.

3. PHARMACEUTICAL FORM

Swissgarde Stressgarde Capsules are HPMC veggie capsules containing light brown powder.

4. CLINICAL PARTICULARS

Category D: human complementary medicine. This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.

4.1. Therapeutic Indications

Swissgarde Stressgarde Capsules are used to help the body manage with stress and anxiety.

4.2. Posology and method of administration

Posology

Adults: The dose is 2 capsules daily.

Method of administration

Swissgarde Stressgarde Capsules should be taken once a day with food or as recommended by your Health Practitioner.

4.3. Contraindications

Avoid if allergic or sensitive to any of the listed ingredients. Do not exceed recommended dosage(s).

4.4. Special warnings and precautions for use

Swissgarde Stressgarde Capsules must not be used if hypersensitive (allergic) to any ingredients.

4.5. Interaction with other medicines and other forms of interaction

If you are taking prescription medication, consult a healthcare practitioner prior to use. Swissgarde Stressgarde Capsules are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Swissgarde Stressgarde Capsules should not be used during pregnancy, and a healthcare provider should be consulted for advice prior to taking Swissgarde Stressgarde Capsules when breastfeeding.

4.7. Effects on ability to drive and use machines.

No effects on the ability to drive and use machines has been reported.

4.8. Undesirable effects

None known. Should general health worsen, or if any untoward effects are experienced while using this product, please consult a doctor, pharmacist, or other health care professional for advice.

4.9. Overdose

If you take more Swissgarde Stressgarde Capsules than you should:

If anyone, especially a child, accidentally takes too much Swissgarde Stressgarde Capsules contact your doctor or local poison centre immediately. If symptoms persist consult your doctor. If you see a doctor or have to go to hospital for any reason, tell them what medicines you are taking.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

33.6 Western herbal medicine. Swissgarde Stressgarde Capsules contain substances to help the body manage with stress and anxiety.

5.2. Pharmacokinetic properties

There is no pharmacokinetic data available on the active ingredients via the route of administration described.

5.3. Preclinical safety data

There is no preclinical safety data available on the active ingredients via the route of administration described.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive ingredients: magnesium stearate.

6.2. Incompatibilities:

None

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 30 ˚C in a cool, dry place. Store out of reach of children. Do not use after the expiry date stated on the bottle. The expiry date refers to the last day of the month.

6.5. Nature and contents of container

Swissgarde Stressgarde Capsules is a clear capsule with light brown powder in a white tablet container and white cap, containing 60 veggie-capsules.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Distributed by:

The Sportron Group

Route 21 Business Park, 59 Regency Drive, Centurion, South Africa, 0157.

Tel: +27 (11) 317 8500

www.sportron.co.za

Name and Address of Holder of Certificate of Registration

Microbel Laboratories (Pty) Ltd,

86 Gazelle Ave, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: info@microbel.co.za

+27 11 076 4000

8. REGISTRATION NUMBER(S)

Application Number: TBC by SAHPRA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

TBA by SAHPRA. Date of Revision: August 2025

PROFESSIONELE INLIGTING

Kategorie D: Menslike komplementêre medisyne. Hierdie medisyne is nog nie deur SAHPRA geëvalueer nie. Die doel van hierdie medisyne is nie om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

SKEDULERINGSTATUS

S0

1. NAAM VAN MEDIKASIE

Swissgarde Stressgarde Kapsules

2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per kapsule: Ashwagandha-wortel (Withania Somnifera) 350,0 mg, magnesiumsufaat 160 mg wat elementêre magnesium 15,75 mg verskaf, vitamien B6 (piridoksien) 1,3 mg, vitamien B12 (sianokobalamien) 3,0 mcg, vitamien D3 cholecalciferol) 300 IE, sinkoksien 8 mg wat elementêre sink 6,4 mg verskaf, Fucoidan 10,0 mg.

3. FARMASEUTIESE DOSEERVORM

Swissgarde Stressgarde kapsules is HPMC-groente kapsules wat ligbruin poeier bevat.

4. KLINIESE BESONDERHEDE

Kategorie D: Menslike komplementêre medisyne. Hierdie medisyne is nog nie deur SAHPRA geëvalueer nie. Die doel van hierdie medisyne is nie om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

4.1 Terapeutiese indikasies

Swissgarde Streesgarde kapsules word gebruik om die liggaam te help om stres en angs te bestuur.

4.2 Dosering en metode van toediening

Dosering

Volwassenes: Die dosis is daagliks 2 kapsules.

Metode van toediening

Swissgarde Stressgarde kapsules moet een keer per dag saam met kos geneem word of soos aanbeveel deur jou gesondheidspraktisyn.

4.3 Kontra-indikasies

Vermy as allergies of sensitief vir enige van die genoemde bestanddele. Moenie die aanbevole dosis(se) oorskry nie.

4.4 Waarskuwings en spesiale voorsorgmaatreëls

Swissgarde Stessgarde kapsules moet nie gebruik word as u hipersensitief (allergies) is vir enige bestanddele nie.

4.5 Interaksies met ander medisyne en ander tipe interaksies

As jy voorskrif medikasie neem, raadpleeg ‘n gesondheidsorgpraktisyn voor gebruik. Dit is nie bekend dat Swissgarde Stressgarde kapsules sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Swissgarde Stressgarde kapsules moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Swissgarde Stressgarde kapsules geneem word tydens borsvoeding.

4.7 Effek op die vermoë om te bestuur en masjinerie te gebruik

Geen effekte op die vermoë om te bestuur of om masjinerie te gebruik is aangemeld nie

4.8 Newe-effekte

Geen bekend. Indien u algemene gesondheid versleg, of indien u enige newe-effekte ervaar tydens die gebruik van hierdie produk, moet jou dokter, apteker of ander gesondheidsorgverskaffer vir advies geraadpleeg word.

4.9 Oordosering

As jy meer Swissgarde Stressgarde kapsules neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Swissgarde Stressgarde kapsules neem, kontak jou dokter of plaaslike gif sentrum onmiddellik. As simptome voortduur, raadpleeg jou dokter. As jy ‘n dokter sien of om een of ander rede hospitaal toe moet gaan, vertel hulle watter medisyne jy neem.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

33.6 Westerse kruie medisyne. Swissgarde Stressgarde kapsules bevat stowwe om die liggaam te help om stres en angs te bestuur.

5.2 Farmakokinetiese eienskappe

Daar is geen farmakokinetiese data beskikbaar oor die aktiewe bestanddele via die toedienings roete wat beskryf word nie.

5.3 Pre-kliniese gesondheidsdata

Daar is geen pre-kliniese veiligheids data beskikbaar oor die aktiewe bestanddele via die toedienings roete wat beskryf word nie.

6. FARMASEUTIESE BESONDERHEDE

6.1 Lys van hulpstowwe

Onaktiewe bestanddele: Magnesium stearaat.

6.2 Onverenigbaarhede

Geen.

6.3 Rakleeftyd

2 Jaar.

6.4 Spesiale voorsorgmaatreëls vir bewaring

Bewaar benede 30 °C in ‘n koel droë plek. Hou buite bereik van kinders. Moet nie die produk na die vervaldatum aangedui op die houer gebruik nie. Die vervaldatum verwys na die laaste dag van die maand.

6.5 Samestelling en inhoud van die houer

Swissgarde Stressgarde Kapsules is ‘n deursigtige kapsule met ligbruin poeier in ‘n wit tablet houer en wit dop, wat 60 groente kapsules bevat.

Spesiale voorsorgmaatreëls vir wegdoening

Geen spesiale vereistes nie.

7. VOORGESTELDE HOUER VAN REGISTRASIESERTIFIKAAT

Versprei deur:

The Sportron Group

Route 21 Business Park, 59 Regency Drive, Centurion, South Africa, 0157

Tel: +27 (11) 317 8500

www.sportron.co.za

Naam en Adres van Houer van Registrasiesertifikaat

Microbel Laboratories (Pty) Ltd,

86 Gazelle Ave, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: info@microbel.co.za

+27 11 076 4000

8. REGISTRASIENOMMER(S)

Aansoek nommer: TBC deur SAHPRA

9. DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN GOEDKEURING

TBA deur SAHPRA. Datum van hersiening: Augustus 2025.