SWISSGARDE

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

Sportron Mental Calm Matrix Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per capsule: Ashwagandha (Withania Somnifera) 250,0 mg, L-Theanine 100,0 mg, Chamomile Powder (Matricaria Chamomilla)100,0 mg, Passiflora Powder (Passiflora Incarnata) 60,0 mg, Valeria Powder (Valeria Offincialis) 50,0 mg.

3. PHARMACEUTICAL FORM

Sportron Mental Calm Matrix Capsules are HPMC veggie capsules containing 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

Sportron Mental Calm Matrix Capsules are used to promote relaxation and calmness.

4.2. Posology and method of administration

Posology

Adults: The dose is 1 capsule daily.

Method of administration

Sportron Mental Calm Matrix 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

Sportron Mental Calm Matrix 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. Sportron Mental Calm Matrix Capsules are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Sportron Mental Calm Matrix Capsules should not be used during pregnancy, and a healthcare provider should be consulted for advice prior to taking Sportron Mental Calm Matrix 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 Sportron Mental Calm Matrix Capsules than you should:

If anyone, especially a child, accidentally takes too much Sportron Mental Calm Matrix 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

34.12 Multiple substance medicine. Sportron Mental Calm Matrix Capsules contains substances to promote relaxation and calmness.

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: biofood matrix, 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

Sportron Mental Calm Matrix Capsules is a clear capsule with brown powder in a white PET glossy container and ribbed cap, containing 30 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

SWISSGARDE

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

Sportron Geestelike Kalm Matriks Kapsules

2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per kapsule: Ashwagandha (Withania Somnifera) 250,0 mg, L-Theanine 100,0 mg, Kamille Poeier (Matricaria Chamomilla) 100,0 mg, Passiflora Poeier (Passiflora Incarnata) 60,0 mg, Valeria Poeier (Valeria Offincialis) 55,0 mg.

3. FARMASEUTIESE DOSEERVORM

Sportron Geestelike Kalm Matriks kapsules is HPMC-groente kapsules wat bruin 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

Sportron Geestelike Kalm Matriks kapsules word gebruik om ontspanning en kalmte te bevorder.

4.2 Dosering en metode van toediening

Dosering

Volwassenes: Die dosis is daagliks 1 kapsule.

Metode van toediening

Sportron Geestelike Kalm Matriks 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

Sportron Geestelike Kalm Matriks 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 Sportron Geestelike Kalm Matriks kapsules sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Sportron Geestelike Kalm Matriks kapsules moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Sportron Geestelike Kalm Matriks 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 Sportron Geestelike Kalm Matriks kapsules neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Sportron Geestelike Kalm Matriks 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

34.12 Meervoudige stof medisyne. Sportron Geestelike Kalm Matriks kapsules bevat stowwe om ontspanning en kalmte te bevorder.

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: Biovoedsel matriks, 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

6.6 Sportron Geestelike Kalm Matriks Kapsules is ‘n deursigtige kapsule met bruin poeier in ‘n wit PET-glashouer en geribde dop, wat 30 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.