SPORTRON

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 Female Hormone Balance capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per capsule: Chasteberry Powder (Vitex Agnus-Castus Fruit) 277,35mg, Magnesium Glycinate (36 MG Elemental Magnesium) 200mg, Lemon Balm (Melissa Officinalis Leaf) 100mg, Vitamin B6 (As Pyridoxine Hydrochloride) 30mg, Zinc Oxide (Providing 10mg Elemental Zinc) 12,45mg.

3. PHARMACEUTICAL FORM

Sportron Female Hormone Balance capsules are 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

Sportron Female Hormone Balance capsules are used to support natural hormone balance whilst promoting calm, sleep and wellbeing.

4.2. Posology and method of administration

Posology

Adults: The usual dose is 1 capsule daily

Method of administration

Sportron Female Hormone Balance capsules should be taken once a day with food or as directed 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 Female Hormone Balance 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 Female Hormone Balance capsules are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Sportron Female Hormone Balance capsules should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Sportron Female Hormone Balance 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 Female Hormone Balance Capsules than you should:

If anyone, especially a child, accidentally takes too much Sportron Female Hormone Balance 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. Sportron Female Hormone Balance capsules contain substances to support natural hormone balance.

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, HPMC vegan vegetable capsules

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 Female Hormone Balance Capsules is a clear capsule with light brown powder in a white PET bottle with a white ribbed cap with pressure liner containing 30 veggie-capsules.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Distributed by:

Sportron Group (Pty) Ltd

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

SPORTRON

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 Vroulike Hormoonbalans kapsules.

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per kapsule: Koelbessiepoeier (Vitex Agnus-Castus Vrug) 277,35 mg, Magnesiumglisinaat (36 mg Elementêre Magnesium) 200 mg, Suurlemoenbalsem (Melissa Officinalis-blaar) 100 mg, Vitamien B6 (as Pyridoksien Hidrochloried) 30 mg, Sinkoksied (verskaf 10 mg Elementêre Sink) 12,45 mg.

3. FARMASEUTIESE DOSEERVORM

Sportron Vroulike Hormoonbalans kapsules is 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

Sportron Vroulike Hormoonbalans kapsules word gebruik om natuurlike hormoonbalans te ondersteun terwyl dit kalmte, slaap en welstand bevorder.

4.2 Dosering en metode van toediening

Dosering

Volwassenes: Die gewone dosis is 1 kapsule per dag.

Metode van toediening

Sportron Vroulike Hormoonbalans kapsules moet een keer per dag saam met kos geneem word of soos deur jou gesondheidspraktisyn voorgeskryf.

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 Vroulike Hormoonbalans 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 Vroulike Hormoonbalans kapsules sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Sportron Vroulike Hormoonbalans kapsules moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Sportron Hormoonbalans 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 hy meer Sportron Vroulike Hormoonbalans kapsules neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Sportron Vroulike Hormoonbalans 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

Kategorie D33.6 Westerse Kruie medisyne. Sportron Vroulike Hormoonbalans kapsules bevat stowwe om natuurlike hormoonbalans te ondersteun..

5.2. Farmakokinetiese eienskappe

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

5.3. Prekliniese veiligheids data

Daar is geen prekliniese veiligheids data beskikbaar oor die aktiewe bestanddele via die beskryfde toedienings roete nie.

6. FARMASEUTIESE BESONDERHEDE

6.1. Lys van hulpstowwe

Onaktiewe bestanddele: Magnesiumstearaat, HPMC veganistiese groentekapsules.

6.2. Onverenigbaarhede

Geen.

6.3. Rakleeftyd

2 jaar.

6.4. Spesiale voorsorgmaatreëls vir bewaring

Bewaar onder 30 °C op ’n koel, droë plek. Hou buite bereik van kinders. Moet nie die produk ná die vervaldatum wat op die houer aangedui word, gebruik nie. Die vervaldatum verwys na die laaste dag van die maand.

6.5. Samestelling en inhoud van die houer

Sportron Female Hormone Balance kapsules is deursigtige kapsules met ligbruin poeier in ‘n wit PET-bottel met ‘n wit geribde dop met drukvoering wat 30 groete-kapsules bevat.

Spesiale voorsorgmaatreëls vir wegdoening

Geen spesiale vereistes nie.

7. VOORGESTELDE HOUER VAN REGISTRASIESERTIFIKAAT

Versprei deur:

Sportron Group (Pty) Ltd

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.