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 40+ Men Matrix capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per capsule: Calcium Carbonate 368,6 mg providing Elemental Calcium 147,5 mg; Magnesium Stearate 100 mg providing Elemental Magnesium 9,86 mg; Vitamin C 90.0 mg; Saw Palmetto (Serenoa repens) [Leaf Powder] 60.0 mg; Zinc Oxide 11.0 mg providing Elemental Zinc 8.69 mg; Vitamin B1 (Thiamine) 1,2 mg; Vitamin B3 (Niacin) 16.0 mg; Iron Sulphate ACC 10% 1 mg providing Elemental Iron 0,1 mg; Vitamin B5 (Pantothenic acid) 5.0 mg; Vitamin B6 (pyridoxine) 1,7 mg; Vitamin B9 (Folic acid) 0,4 mg; Vitamin A 900 IU; Vitamin D3 600 IU; Vitamin E 8 mg; Iron Amino Acid Chelate 1,0 mg; Lutein 0,6 mg; Lycopene 10,0 mg; Sea Weed Extract (Sargassum fusiforme) 20,0 mg.

3. PHARMACEUTICAL FORM

Sportron 40+ Men Matrix capsules are hard gel 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 40+ Men Matrix capsules are used for supplementation for men.

4.2. Posology and method of administration

Posology

Adults: The usual dose is 1 capsule daily.

Method of administration

Sportron 40+ Men Matrix capsules should be taken once a day with or without food.

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 40+ Men 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 40+ Men Matrix capsules are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Sportron 40+ Men Matrix capsules should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Sportron 40+ Men 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 40+ Men Matrix Capsules than you should:

If anyone, especially a child, accidentally takes too much Sportron 40+ Men 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

33.7 Combination medicine. Sportron 40+ Men Matrix capsules contain substances to supplement the diet.

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, biofood matrix.

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 40+ Men Matrix Capsules is a clear capsule with light brown powder in a white HDPE tamper-evident container, 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 40+ Men Matrix kapsules

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per kapsule: Kalsiumkarbonaat 368,6 mg wat 147,5 mg elementêre kalsium verskaf; Magnesiumstearaat 100 mg wat 9,86 mg elementêre magnesium verskaf; Vitamien C 90,0 mg; Saw Palmetto (Serenoa repens) [Blaarpoeier] 60,0 mg; Sinkoksied 11,0 mg wat 8,69 mg elementêre sink verskaf; Vitamien B1 (Tiamien) 1,2 mg; Vitamien B3 (Niasien) 16,0 mg; Ystersulfaat ACC 10% 1 mg wat 0,1 mg elementêre yster verskaf; Vitamien B5 (Pantoteensuur) 5,0 mg; Vitamien B6 (piridoksien) 1,7 mg; Vitamien B9 (Foliensuur) 0,4 mg; Vitamien A 900 IE; Vitamien D3 600 IE; Vitamien E 8 mg; Yster-aminosuurchelaat 1,0 mg; Luteïen 0,6 mg; Likopeen 10,0 mg; Seewier-uittreksel (Sargassum fusiforme) 20,0 mg.

3. FARMASEUTIESE DOSEERVORM

Sportron 40+ Men Matrix kapsules is harde gelatienkapsules 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 40+ Men Matrix kapsules word gebruik as aanvulling vir mans.

4.2 Dosering en metode van toediening

Dosering

Volwassenes: Die gewone dosis is 1 kapsule daagliks.

Metode van toediening

Sportron 40+ Men Matrix kapsules moet een keer per dag met of sonder voedsel geneem word.

4.3 Kontra-indikasies

Vermy gebruik indien u allergies of sensitief is vir enige van die gelyste bestanddele. Moenie die aanbevole dosis(se) oorskry nie.

4.4 Waarskuwings en spesiale voorsorgmaatreëls

Sportron 40+ Men Matrix kapsules moet nie gebruik word indien u hipersensitief (allergies) is vir enige bestanddeel nie.

4.5 Interaksies met ander medisyne en ander tipe interaksies

Indien u voorskrifmedikasie neem, raadpleeg ’n gesondheidsorgpraktisyn voor gebruik. Dit is nie bekend dat Sportron 40+ Men Matrix kapsules nadelig reageer met enige tipe medisyne, voedsel of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Sportron 40+ Men Matrix kapsules moet nie tydens swangerskap gebruik word nie, en ’n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Sportron 40+ Men Matrix kapsules tydens borsvoeding geneem word.

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

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

4.8 Newe-effekte

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

4.9 Oordosering

Indien u meer Sportron 40+ Men Matrix kapsules neem as wat u moet:

Indien iemand, veral ’n kind, per ongeluk te veel Sportron 40+ Men Matrix kapsules neem, kontak u dokter of plaaslike gifsentrum onmiddellik. Indien simptome voortduur, raadpleeg u dokter. Indien u ’n dokter sien of om enige rede hospitaal toe moet gaan, vertel hulle watter medisyne u neem.

5. FARMAKOLOGIESE EIENSKAPPE

5.1. Farmakodinamiese eienskappe

33.7 Kombinasiemedisyne. Sportron 40+ Men Matrix kapsules bevat stowwe om die dieet aan te vul.

5.2. Farmakokinetiese eienskappe

Daar is geen farmakokinetiese data beskikbaar oor die aktiewe bestanddele via die beskryfde toedieningsroete nie.

5.3. Prekliniese veiligheidsdata

Daar is geen prekliniese veiligheidsdata beskikbaar oor die aktiewe bestanddele via die beskryfde toedieningsroete nie.

6. FARMASEUTIESE BESONDERHEDE

6.1. Lys van hulpstowwe

Onaktiewe bestanddele: magnesiumstearaat, biovoedselmatriks.

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 40+ Men Matrix kapsules is deursigtige kapsules met ligbruin poeier in ’n wit HDPE-houer met peuterbestande sluiting, wat 30 groentekapsules 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)

Aansoeknommer: TBC deur SAHPRA

9. DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN GOEDKEURING

TBA deur SAHPRA. Datum van hersiening: Augustus 2025.