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 Omegatone Matrix

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per serving (10ml): Flax Seed Oil (Linum usitatissimum) 485 mg (containing: Alpha-Linolenic Acid (ALA) 265 mg), Vitamin D3 (Cholecalciferol) 300 IU, Vitamin E (Tocopherol) 15 mg, Vitamin K2 (Menaquinone) 30 mcg.

3. PHARMACEUTICAL FORM

Sportron Omegatone Matrix is a creamy light brown liquid.

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 Omegatone Matrix is used to support overall wellness.

4.2. Posology and method of administration

Posology

Children 5 to 12 years of age:

5ml daily

Standard Adult dose and children above 12:

10ml daily or as directed by your health practitioner.

Method of administration

Sportron Omegatone Matrix should be taken orally.

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 Omegatone Matrix 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 Omegatone Matrix are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

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

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

Category D34.12. Health Supplements. Sportron Omegatone Matrix contain substances to support overall wellness.

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: RO Water, Citric Acid, EDTA2NA, Flavouring, Sodium Saccharin, Acesulfame K. Polysorbate 80, Sodium Benzoate, Potassium Sorbate, Glycerin, Carboxymethylcellulose, Xanthan Gum, Sodium Citrate, Menthol.

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 Omegatone Matrix is a creamy light brown liquid in a white flat neck bottle with a flat-top cap tamper strip, containing 250ml.

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: March 2026

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 Omegatone Matrix

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per porsie (10ml): Vlasaadolie (Linum usitatissimum) 485 mg (bevat: Alfa Linoleensuur (ALA) 265 mg), Vitamien D3 (Cholecalciferol) 300 IE, Vitamien E (Tocopherol) 15 mg, Vitamien K2 (Menaquinone) 30 mcg.

3. FARMASEUTIESE DOSEERVORM

Sportron Omegatone Matrix is 'n romerige ligbruin vloeistof.

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 Omegatone Matrix word gebruik om algehele welstand te ondersteun.

4.2 Dosering en metode van toediening

Dosering

Kinders 5 to 12 jaar van ouderdom:

5ml daagliks

Standaard volwasse dosis en kinders bo 12 jaar van ouderdom:

10 ml daagliks of soos deur jou gesondheidspraktisyn voorgeskryf.

Metode van toediening

Sportron Omegatone Matrix moet mondelings geneem word.

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 Omegatone Matrix 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 Omegatone Matrix sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Sportron Omegatone Matrix moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Sportron Omegatone Matrix 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 Omegatone Matrix neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Sportron Omegatone Matrix 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 D34.12. Gesondheid aanvullings. Sportron Omegatone Matrix bevat stowwe om algehele welstand 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 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: RO-water, sitroensuur, edta2na, geurmiddels, natriumsakkarien, asesulfaam k. Polisorbaat 80, natriumbenzoaat, kaliumsorbaat, gliserien, karboksimetielsellulose, xantaangom, natriumsitraat, mentol.

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

Sportron Omegatone Matrix is ‘n romerige ligbruin vloeistof in 'n wit platnek bottel met 'n plat doppie stamper strook, wat 250ml 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: Maart 2026.