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 Melotone Matrix

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per serving (10ml): Flax Seed Oil (Linum usitatissimum) 245 mg (containing: Oleic Acid 46.2 mg, Linoleic Acid 36.8 mg, Alpha-Linolenic Acid (ALA) 136.8 mg, Gamma-Linolenic Acid (GLA) 2.86 mg), Vitamin B1 (Thiamine) 1.2 mg, Vitamin B2 (Riboflavin) 1.3 mg, Vitamin B3 (Niacin) 16 mg, Vitamin B6 (Pyridoxine) 1.3 mg, Vitamin B12 (Cobalamin) 10 mcg, Vitamin C (Ascorbic Acid) 90 mg, Vitamin D3 (Cholecalciferol) 600 IU, Vitamin E (Tocopherol) 15 mg, Saffron Extract (Crocus sativus) 40 mg, Evening Primrose Oil (Oenothera biennis) 200 mg, Calcium Lactate 100 mg (containing 13 mg elemental Calcium), Magnesium Glycinate 122.5 mg (containing 17.3 mg elemental Magnesium), Zinc Oxide 10 mg (containing 8 mg elemental Zinc), Seaweed Extract (Ascophyllum nodosum) 10 mg, Glycine 100 mg, L-Carnitine 40 mg, Taurine 50 mg.

3. PHARMACEUTICAL FORM

Sportron Melotone Matrix is a milky yellow liquid with a fruity fragrance.

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 Melotone Matrix is used to support concentration, memory and cognitive health.

4.2. Posology and method of administration

Posology

Children 6 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 Melotone 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).

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4.4. Special warnings and precautions for use

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

4.6. Fertility, pregnancy and lactation

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

If anyone, especially a child, accidentally takes too much Sportron Melotone 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 Melotone Matrix contain substances to support concentration, memory and cognitive health.

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, EDTA2NA, Flavouring, Sodium Saccharin, Acesulfame K. Polysorbate 80, Sodium Benzoate, Potassium Sorbate, Glycerin, Citric Acid Carboxymethylcellulose.

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 Melotone Matrix is a milky yellow 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

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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 Melotone Matrix

2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per porsie (10 ml): Vlasaadolie (Linum usitatissimum) 245 mg (bevat: Oleïensuur 46.2 mg, Linolzuur 36.8 mg, Alpha-Linoleensuur (ALA) 136.8 mg, Gamma-Linoleensuur (GLA) 2.86 mg, Vitamien B1 (Thiamien) 1.2 mg, Vitamien B2 (Riboflavien) 1.3 mg, Vitamien B3 (Niacin) 16 mg, Vitamien B6 (Piridoksien) 1.3 mg, Vitamien B12 (Kobalamien) 10 mcg, Vitamien C (Askorbiensuur) 90 mg, Vitamien D3 (Cholecalciferol) 600 IU, Vitamien E (Tocopherol) 15 mg, Saffraan-ekstrak (Crocus sativus) 40 mg, Aandprimula-olie(Oenothera biennis) 200 mg, Kalsiumlaktaat 100 mg (bevat 13 mg elementêre kalsium bevat), Magnesiumglisinaat 122.5 mg (wat 17.3 mg elementêre Magnesium bevat), Sinkoksien 10 mg (wat 8 mg elementêre Sink bevat), Seewier-ekstrak (Ascophyllum nodosum) 10 mg, Glisien 100 mg, L-Karnitien 40 mg, Taurine 50 mg.

3. FARMASEUTIESE DOSEERVORM

Sportron Melotone Matrix is ‘n melkagtige geel vloeistof met ‘n vrugtige geur.

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 Melotone Matrix word gebruik om konsentrasie, geheue en kognitiewe gesondheid te ondersteun.

4.2 Dosering en metode van toediening5ml

Dosering

Kinders van 6 tot 12 jaar oud:

5ml Daagliks.

Standaard volwasse dosis en kinders ouer as 12:

10 ml Daagliks of soos deur jou gesondheidspraktisyn voorgeskryf.

Metode van toediening

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

4.6 Vrugbaarheid, swangerskap en borsvoeding

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

As iemand, veral ‘n kind per ongeluk te veel Sportron Matrix neem, Melotone 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 34.12 Gesondheid aanvullings. Sportron Melotone Matrix bevat stowwe om konsentrasie, geheue en kognitiewe gesondheid 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, EDTA2NA, geurmiddels, natrium sakkarien, asesulfaam K, Polisorbaat 80, natriumbenzoaat, kaliumsorbaat, gliserien, karboksimetielsellulose, sitroensuur..

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 Melotone Matrix is ‘n melkagtige geel vloeistof in ‘n wit plat nek bottel met ‘n plat doppies tamperstrip wat 250 ml 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: Maart 2026