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 A-tron Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per 1g: Cannabidiol (Cannabis sativa) ISOLATE 0,05 mg (1:100 M/M), Methylsulfonylmethane 25 mg, Arnica montana extract 30 mg, Clove Essential Oil (Syzygium aromaticum) 1.5 mg, Wintergreen Essential Oil (Gaultheria procumbens) 1.75 mg, Rosemary Essential Oil (Rosmarinus officinalis) 0.5 mg.

3. PHARMACEUTICAL FORM

Sportron A-tron Gel is a light green gel.

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 A-tron Gel is used to soothe joint pain, swelling and stiffness.

4.2. Posology and method of administration

Posology

Apply a thin layer to the affected area no more than 6 times per day. Massage gently for 2 minutes after application.

Method of administration

Sportron A-tron Gel for external use only.

4.3. Contraindications

Avoid if allergic or sensitive to any of the listed ingredients. Do not exceed recommended application(s).

4.4. Special warnings and precautions for use

Sportron A-tron Gel must not be used if hypersensitive (allergic) to any ingredients.

SPORTRON

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 A-tron Gel is not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Sportron A-tron Gel should not be used during pregnancy, and a healthcare provider should be consulted for advice prior to taking Sportron A-tron Gel 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 apply more Sportron A-tron Gel than you should:

If anyone, especially a child, accidentally ingests or applies too much Sportron A-tron Gel 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 A-tron Gel contains substances to soothing joint pain, swelling and stiffness.

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, Carborner, Menthol, CBD Oil ≤25 mg per 5g, Sodium Benzoate, Potassium Sorbate, EDTA2Na, Vanillyl Butyl Ether, Polysorbate 20, Colourant, Triethanolamine.

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 A-tron Gel is a light green gel in a white jar with a white lid, containing 50g.

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 A-tron Gel

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per 1g: Cannabidiol (Cannabis sativa) ISOLAAT 0,05 mg (1:100 M/M), Metielsulfonielmetaan 25 mg, Arnica montana-ekstrak 30 mg, Kruie Essensiële Olie (Syzygium aromaticum) 1.5 mg, Wintergreen Essensiële Olie (Gaultheria procumbens) 1.75 mg, Rosmaryn Essensiële Olie (Rosmarinus officinalis) 0.5 mg.

3. FARMASEUTIESE DOSEERVORM

Sportron A-tron Gel is a ligte groen gel.

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 A-tron Gel word gebruik om gewrigspyn, swelling en styfheid te verlig.

4.2 DOSERING EN METODE VAN TOEDIENING

Dosering

Smeer 'n dun lagie op die aangetaste area nie meer as 6 keer per dag nie. Masseer sagkens vir 2 minute na aanwending.

Metode van toediening

Sportron A-Tron Gel is slegs vir eksterne gebruik.

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 A-tron Gel 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 A-tron Gel sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Sportron A-tron Gel moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Sportron A-tron Gel 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 A-tron Gel aanwend as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Sportron A-tron Gel 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. Gesonheidsaanvullings. Sportron A-tron Gel bevat stowwe gewrigspyn, swelling en styfheid te verlig.

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, Carborner, Menthol, CBD-olie ≤25 mg per 5g, natriumbenzoaat, kaliumsorbate, EDTA2Na, vanillyl butiel eter, polisorbaat 20, kleurmiddel, trietanolamien.

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 A-tron Gel is ‘n liggroen gel in ‘n wit fles met ‘n wit deksel, wat 50g bevat.

Spesiale voorsorgmaatreëls vir wegdoening

Geen spesiale vereistes nie.

7. VOORGESTELDE HOUER VAN REGISTRASIESERTIFIKAAT

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.