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 Infagarde

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per ml: Echinacea purpurea (L.) [Flower Powder] 36,3 mg; Euphrasia officinalis (Eyebright) powder 13,6 mg; Astragalus membranaceus 27,3 mg; Zingiber officinale (Ginger) [Root Powder] 18,2 mg; Garlic (Allium sativum) 0,14 mg.

3. PHARMACEUTICAL FORM

Sportron Infagarde is a herbal blend tincture brown liquid containing Echinacea, Pelargonium and Ginger.

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 Infagarde is used to help relieve symptoms of cold and flu and help boost the body's natural immune system.

4.2. Posology and method of administration

Posology

Adults: The dose is 60 drops of the tincture up to twice a day.

Children: 12 years and above: The dose is 30 drops of the tincture daily.

6 to 12 years: The dose is 15 drops of the tincture daily.

Method of administration

Sportron Infagarde should be mixed with half a glass of water or juice with a meal or as recommended 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 Infagarde 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 Infagarde are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

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

If anyone, especially a child, accidentally takes too much Sportron Infagarde 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 Infagarde contains substances to help relieve symptoms of cold and flu and help boost the body's natural immune system.

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, Glycerine, Menthol, Potassium Sorbate, Sodium Benzoate, EDTA2NA, 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 Infagarde is a herbal blend tincture brown liquid in a 100 mL amber glass bottle with a white fast-dropper cap.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Distributed by:

The Sportron Group

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 Infagarde

2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per ml: Echinacea purpurea (L.) (Blompoeier) 36,3 mg; Euphrasia officinalis (Oogtroost) poeier 13,6 mg; Astagalus membranaceur 27,3 mg; Zingiber officianle (Gemmer) (Wortelpoeier) 18,2 mg; Knoffel (Allium sativum) 0,14 mg.

3. FARMASEUTIESE DOSEERVORM

Sportron Infagarde is ‘n kruie mengsel tinktuur bruin vloeistof wat Echniacea, Pelargonium en Gemmer 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 Infagarde word gebruik om simptome van verkoue en griep te verlig en die liggaam se natuurlike immuunstelsel te help versterk.

4.2 Dosering en metode van toediening

Dosering

Volwassenes: Die dosis is 60 druppels van die tinktuur tot twee keer per dag.

Kinders: 12 Jaar en ouer: Die dosis is 30 druppel van die tinktuur per dag.

6 tot 12 Jaar: Die dosis is 15 druppels van die tinktuur per dag.

Metode van toediening

Sportron Infagarde moet gemeng word met ‘n halwe glas water met ‘n maaltyd of soos aanbeveel deur jou gesondheidspraktisyn.

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

4.6 Vrugbaarheid, swangerskap en borsvoeding

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

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

33.6 Westerse kruiemedisyne. Sportron Infagarde bevat stowwe om simptome van verkoue en griep te verlig en die liggaam se natuurlike immuunstelsel te help versterk.

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, gliserien, menthol, kaliumsorbaat, natriumbenzoaat, EDTA2NA, biovoedsel-matriks.

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 Infagarde is ‘n kruie mengsel tinktuur bruin vloeistof in ‘n 100 ml amberkleurig glasbottel met ‘n wit vinnige dop.

Spesiale voorsorgmaatreëls vir wegdoening

Geen spesiale vereistes nie.

7. VOORGESTELDE HOUER VAN REGISTRASIESERTIFIKAAT

Versprei deur:

The Sportron Group

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.