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 Pro B9 Matrix Drops

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per ml: 1 billion cu consisting of: {Lactobacillus Acidophilus Ubla-34, Bifidobacterium Lactis Ubbla-70, Bifidobacterium Bifidum Ubbb-55, Lactobacillus Rhamnosus Hn00, Lactobacillus Casei Lc-11, Lactobacillus Planmtarum Lp-115, Lactobacillus Lactis Li-23, Bifidobacterium Longum Ubbl-64, Streptococcus Thermophilis St-21}, Prebiotics Blend (Fructooligodsaccharides 3,5 mg, Maltodextrin (Prebiotic Fiber) 37,5 mg.

## 3. PHARMACEUTICAL FORM

Sportron Pro B9 Matrix Drops is a clear yellow 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 Pro B9 Matrix Drops is used to promote gut health.

### 4.2. Posology and method of administration

**Posology**

**For children over 3 years and adults:** The dose is 1ml daily

**Method of administration**

Sportron Pro B9 Matrix Drops can be mixed in with drinks or as recommended by your Health Practitioner. Shake well before use.

### 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 Pro B9 Matrix Drops 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 Pro B9 Matrix Drops is not known to react badly with any types of medicines, or food or drink.

### 4.6. Fertility, pregnancy and lactation

Sportron Pro B9 Matrix Drops should not be used during pregnancy, and a healthcare provider should be consulted for advice prior to taking Sportron Pro B9 Matrix Drops 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 Pro B9 Matrix Drops than you should:

If anyone, especially a child, accidentally takes too much Sportron Pro B9 Matrix Drops 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

34.9 Probiotic medicine. Sportron Pro B9 Matrix Drops contains substances to promote gut 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: Biofood Matrix, Glycerine (Low GI, Low Calorie Sweetener), CMC, Flavouring, Sodium Benzoate, Potassium Sorbate, Food Colourant.

### 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 Pro B9 Matrix Drops is a clear yellow liquid in a 30ml amber glass bottle with a ribbed pipette.

**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 Pro B9 Matriks Druppels

## 2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per ml: 1 Biljoen cu bestaande uit: (Lactobacillus Acidophilus Ubla-34, Bifidobacterium Lactis Ublla-70, Bifidobacterium Bifidum UBBB-55, Lactobacillus Rhanosus Hn00, Lactobacillus Casei Lc-11, Lactobacillus Planmtarum Lp-115, Lactobacillus Lactis Li-23, Bifidobacterium Longum Ubbl-64, Streptococcus Thermophillis St-21), Prebiotika-versnit (Fructooligodsaccarides 3,5 mg, Maltodextrin (Prebiotiese vessel) 37,5 mg.

## 3. FARMASEUTIESE DOSEERVORM

Sportron Pro B9 Matriks Druppels is ‘n helder geel 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 Pro B9 Matriks Druppels word gebruik om derm gesondheid te bevorder.

### 4.2 Dosering en metode van toediening

**Dosering**

Vir kinders bo 3 jaar en volwassenes: Die dosis is daagliks 1 ml.

**Metode van toediening**

Sportron Pro B9 Matriks Druppels kan gemeng word met drankies of soos aanbeveel deur jou gesondheidspraktisyn.  Skud goed voor 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 Pro B9 Matriks Druppels 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 voorskrifmedikasie neem, raadpleeg ‘n gesonheidsorgpraktisyn voor gebruik. Dit is nie bekend dat Sportron Pro B9 Matriks Druppels sleg reageer met enige tipe medisyne, of kos of drank nie.

### 4.6 Vrugbaarheid, swangerskap en borsvoeding

Sportron Pro B9 Matriks Druppels moet nie tydens swangerskap gebruik word nie en ‘n gesonheidsorgverskaffer moet geraadpleeg word vir advies voordat Sportron Pro B9 Matriks Druppels 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 Pro B9 Matriks Druppels neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Sportron Pro B9 Matriks Druppels neem, kontak jou dokter of plaaslike gifsentrum onmiddelik. As simptome voortduur, raadpleeg jou dokter. As jy ‘n dokter sien of om een of ander rede hopsitaal toe moet gaan, vertel hulle watter medisyne jy neem.

## 5. FARMAKOLOGIESE EIENSKAPPE

### 5.1 Farmakodinamiese eienskappe

34.9 Pro-biotiese medisyne. Sportron Pro B9 Matriks Druppels bevat stowwe om derm gesondheid te bevorder.

### 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: Biovoedsel matriks, Gliserien (lae GI, lae-kalorie versoeter), CMC, geurmiddel, natrium benzoaat, kaliiumsorbaat, voedselkleurstof.

### 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 Pro B9 Matriks Druppels is ‘n helder geel vloeistof in ‘n 30 ml amberkleurig glasbottel met ‘n geribde pipet.

**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.