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

Swissgarde Kids Multivitamin Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per ml: Ascorbic acid 10 mg; Vitamin B1 0,3 mg; Vitamin B2 0,25 mg; Vitamin B3 2 mg; Vitamin A (Retinyl palmitate) 0,12 mg (360 IU); Vitamin D (Cholecalciferol) 80 IU; Vitamin B6 0,2 mg; Fucoidan (Fucus vesiculosus) 0,1 mg.

3. PHARMACEUTICAL FORM

Swissgarde Kids Multivitamin Syrup is a bright orange syrup.

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

Swissgarde Kids Multivitamin Syrup is used to maintain good health and boost immune health for children

4.2. Posology and method of administration

Posology

Children 5 – 7 years: 10 ml

Children 12 years and older: 20 ml

OR as recommended by your health practitioner

Method of administration

Swissgarde Kids Multivitamin Syrup should preferably be taken after a meal and kept in refrigerator after opening.

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

Swissgarde Kids Multivitamin Syrup 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. Swissgarde Kids Multivitamin Syrup is not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Swissgarde Kids Multivitamin Syrup should not be used during pregnancy, and a healthcare provider should be consulted for advice prior to taking Swissgarde Kids Multivitamin Syrup 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 Swissgarde Kids Multivitamin Syrup than you should:

If anyone, especially a child, accidentally takes too much Swissgarde Kids Multivitamin Syrup 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

33.12 Combination medicine. Swissgarde Kids Multivitamin Syrup contains substances to help maintain good health and boost immune health for children.

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: Stevia, flavouring, food colourant, Potatssium Sorbate, Methyl paraben, Propyl Paraben, EDTA2Na, Acesulfame, Sodium Saccharin, Citric Acid Sodium Citrate.

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

Swissgarde Kids Multivitamin Syrup is a bright orange syrup.

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

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

Swissgarde Kids Multivitamien Stroop

2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per ml: Askorbiensuur 10 mg; Vitamien B1 0,3 mg; Vitamien B2 0,25 mg; Vitamien B3 2 mg; Vitamien A (Retinylpalmitaat) 0,12 mg (360 IE); Vitamien D (Cholecalciferol) 80 IE; Vitamien B6 0,2 mg; Fucoidan (Fucus vesiculosus) 0,1 mg.

3. FARMASEUTIESE DOSEERVORM

Swissgarde Kids Multivitamien Stroop is ‘n helder oranje stroop.

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

Swissgarde Kids Multivitamien Stroop word gebruik om goeie gesondheid te handhaaf en immuun gesondheid vir kinders te bevorder.

4.2. Dosering en metode van toediening

Dosering

Kinders 5 – 7 jaar: 10 ml

Kinders 12 jaar en ouer: 20 ml

OF soos aanbeveel deur jou gesondheidspraktisyn.

Metode van toediening

Swissgarde Kids Multivitamien Stroop moet verkieslik na ‘n maaltyd geneem word en na oopmaak in die yskas gehou 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 voorsorgmaatreël

Swissgarde Kids Multivitamien Stroop 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 Swissgarde Kids Multivitamien Stroop sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6. Vrugbaarheid, swangerskap en borsvoeding

Swissgarde Kids Multivitamien Stroop moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Swissgarde Kids Multivitamien Stroop 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 Swissgarde Kids Multivitamien Stroop neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Swissgarde Kids Multivitamien Stroop 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

33.12 Kombinasie medisyne. Swissgarde Kids Multivitamien Stroop bevat stowwe om goeie gesondheid te handhaaf en immuun gesondheid vir kinders 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: Geen.

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

Swissgarde Kids Multivitamien Stroop is ‘n helder oranje stroop.

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)

Aansoek nommer: TBC deur SAHPRA

9. DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN GOEDKEURING

TBA deur SAHPRA. Datum van hersiening: Augustus 2025.