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 BioVapour Rub

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per gram: Menthol (Mentha arvensis) 20,1 mg; Camphor (Cinnamomum camphora) oil 4,2 mg; Eucalyptus (Eucalyptus globulus) oil 12,6 mg; Tea tree oil (Melaleuca alternifolia) 0,9 mg; White thyme (Thymus vulgaris) oil 8,4 mg; Peppermint (mentha piperita) oil 7,3 mg; Nutmeg (Myristica fragrans) oil 0,8 mg; Fucoidan (Fucus vesiculosus) 42 mcg.

3. PHARMACEUTICAL FORM

Swissgarde BioVapour Rub is a light ointment.

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 BioVapour Rub is used to assist with nasal congestion, aching muscles and leg cramps.

4.2. Posology and method of administration

Posology

A small amount is to be applied on the skin around the nose or chest.

Method of administration

Swissgarde BioVapour Rub can be applied up to four times a day.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Swissgarde BioVapour Rub 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 BioVapour Rub are not known to react badly with any types of medicines, or food or drink.

4.6. Fertility, pregnancy and lactation

Swissgarde BioVapour Rub should not be used during pregnancy, and a healthcare provider should be consulted for advice prior to taking Swissgarde BioVapour Rub 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 anyone, especially a child, accidentally ingests Swissgarde BioVapour Rub 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

34.12 Multiple substance medicine. Swissgarde Bio Vapour Rub contains substances to help with nasal congestion.

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: None

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 BioVapour Rub is light ointment in a white 50g euro jar.

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 Bio Vapour Rub

2. KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele: Menthol (Mentha arvensis) 20.1 mg; Kamfer (Cinnamomum camphora) olie 4,2 mg; Eucalyptus (Eucalyptus globulus) olie 12,6 mg; Teeboomolie (Melaleuca altenifolia) 0,9 mg; Wit tiemie (Thymus vularis) olie 8,4 mg; Peperment (Menta piperita) olie 7,3 mg; Neutmuskaat (Myristica fragrans) olie 0,8 mg; Fucoidan (Fucus vesiculosus) 42 mcg.

3. FARMASEUTIESE DOSEERVORM

Swissgarde Bio Vapour Rub is ‘n ligte salf.

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 Bio Vapour Rub word gebruik om te help met neusverstopping, seer spiere en been krampe.

4.2. Dosering En Metode Van Toediening

Dosering

‘n Klein hoeveelheid moet op die vel rondom die neus of bors toegedien word.

Metode van toediening

Swissgarde Bio Vapour Rub kan tot vier keer per dag toegedien 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 Bio Vapour Rub 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 Bio Vapour Rub sleg reageer met enige tipe medisyne, of kos of drank nie.

4.6. Vrugbaarheid, swangerskap en borsvoeding

Swissgarde Bio Vapour Rub moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Swissgarde Bio Vapour Rub 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 Bio Vapour Rub neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Swissgarde Bio Vapour Rub 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 Meervoudige stof medisyne. Swissgarde Bio Vapour Rub bevat stowwe om te help met neusverstopping.

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 Bio Vapour Rub is ligte slaf in ‘n wit euro-pot.

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.