

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0

**PROPRIETARY NAME (AND DOSAGE FORM):**

**Respiclear Vapour Rub®** (Topical Preparation)

Active substances: Each gram contains: Menthol (*Mentha arvensis*) 35 mg, Camphor (*Cinnamomum camphora*) oil 50 mg, Eucalyptus (*Eucalyptus globulus*) oil 26 mg, Cinnamon leaf (*Cinnamomum cassia*) oil 7,3 mg, Pine (*Pinus palustris*) oil 14,5 mg.

Category D: Complementary Medicine, Aromatherapy.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety, or intended use.

**Read this leaflet carefully as it contains important information for you.**

Respiclear® Vapour Rub is available without a doctor's prescription for you to relieve cold and flu symptoms. Nevertheless, you still need to use Respiclear® Vapour Rub carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Respiclear® Vapour Rub with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must consult a doctor if your condition worsens or does not improve after 7 days.

**What is in this leaflet:**

- 1. What Respiclear® Vapour Rub is and what it is used for**
- 2. What you need to know before you use Respiclear® Vapour Rub**
- 3. How to use Respiclear® Vapour Rub**
- 4. Possible side effects**
- 5. How to store Respiclear® Vapour Rub**
- 6. Contents of the pack and other information**

## **1. WHAT RESPICLEAR® VAPOUR RUB IS AND WHAT IT IS USED FOR**

Respiclear® Vapour Rub is used for the relief of cold and flu symptoms. Respiclear® Vapour Rub contains a blend of aromatic essential oils, the vapors of which may function to help you breathe more easily when congested.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE RESPICLEAR® VAPOUR RUB**

Do not use Respiclear® Vapour Rub if you are hypersensitive (allergic) to any ingredients.

Use only as directed by a medical practitioner or pharmacist.

**USING OTHER MEDICINES WITH THIS PRODUCT:** Always inform your doctor or pharmacist if you are using any other topical preparation on your skin and would like to use this product. This includes complementary or traditional medicines.

**WARNINGS:** For medicinal use. Respiclear® Vapour Rub is for external use only. Avoid contact with the eyes, eyelids, lips, and mucous membranes. If accidental contact occurs, rinse area with water. Do not apply Respiclear® Vapour Rub directly to the nostrils of infants under the age of 1 year old as there have been reports of apnoea and instant pulmonary collapse in infants, following the localized application of Menthol directly to their nostrils. If any unwanted/adverse effect, or excessive irritation develops, discontinue use and consult your doctor or pharmacist. Not for children younger than 6 months of age.

## **3. HOW TO USE RESPICLEAR® VAPOUR RUB**

Adults: Rub a generous amount onto the neck and chest three times a day. Alternatively add 2 squirts of lotion into 500mL hot (not boiling) water and inhale the vapor. Be careful when using hot water. Children older than 6 months: Gently massage 1 squirt onto the chest, especially before bedtime. Use sparingly on infants and young children.

## **4. POSSIBLE SIDE EFFECTS**

None known. Should your general health worsen, or if you experience any untoward effects while using this product, please consult your doctor, pharmacist, or other health care professional for advice.

## **5. HOW TO STORE RESPICLEAR® VAPOUR RUB**

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.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

What Respiclear® Vapour Rub contains: Each 1 gram contains:

Active ingredients: Menthol (*M. arvensis*) 35 mg, Camphor (*C. camphora*) oil 50 mg, Eucalyptus (*E. globulus*) oil 26 mg, Cinnamon leaf (*C. cassia*) oil 7,3 mg, Pine (*P. palustris*) oil 14,5 mg.

Inactive Ingredients: Sodium benzoate (0,15 %), Potassium sorbate (0,15 %), EDTA<sub>2</sub>Na, Aqua (water), Butyrospermum parkii (Shea butter), Theobroma (Cocoa) seed butter, Polysorbate 20, Hydrogenated vegetable glycerides, Polyacrylamide (and) C13-14 Isoparaffin (and) C9-11 Pareth-6, and Xanthum gum.”

### **What Respiclear® Vapour Rub looks like and contents of the pack:**

Respiclear® Vapour Rub is an off-white herbal smelling lotion 50 mL white plastic airless pump bottle.

### **Name and Address of Holder of Certificate of Registration**

Microbel Laboratories (Pty) Ltd, 86 Gazelle Ave, Corporate Park South, Midrand, Gauteng, 1685, South Africa.

This leaflet was last revised in November 2019.

Reg. No. 422111 Act 101/1965

NAPPI Code 3000284001

Access to the corresponding Professional Information: [www.obellabs.co.za](http://www.obellabs.co.za)

## PASIËNT INLIGTINGSPAMFLET

### SKEDULERINGSSTATUS:

S0

### HANDELSNAAM:

(EN DOSEERVORM):

Respiclear® Vapour rub (Topikale preparaat)

Aktiewe bestanddele: Elke gram bevat: Mentol-olie (*Mentha arvensis*) 35 mg, Kamfer-olie Camphor (*Cinnamomum camphora*) 50 mg, Bloekom-olie (*Eucalyptus globulus*) 26 mg, Kaneelblaar-olie (*Cinnamomum cassia*) 7,3 mg, Denne-olie (*Pinus palustris*) 14,5 mg.

Kategorie D: Komplimentêre medisyne, aromaterapie

Hierdie ongeregistreerde medisyne is nog nie deur die Suid-Afrikaanse Gesondheidsprodukte beheerraad (SAHPRA) geëvalueer vir kwaliteit, veiligheid en voorgestelde gebruik nie.

**Lees hierdie blaadjie sorgvuldig deur, aangesien belangrike inligting hierin deurgegee word.**

Respiclear® Vapour rub is beskikbaar sonder 'n doktersvoorskrif vir die verligting van verkoue- en griepsimptome maar moet noukeurig gebruik word vir die beste resultate.

- Bewaar hierdie pamflet, aangesien inligting later benodig kan word.
- Moenie Respiclear® Vapour rub met enige ander persoon deel nie.
- Raadpleeg jou gesondheidspraktisyn of apteker indien meer inligting of raad benodig word.
- Raadpleeg 'n dokter indien u toestand vererger, of nie verbeter na 7 dae nie.

Wat bevat hierdie pamflet:

- 1. Wat is Respiclear® Vapour Rub en waarvoor word dit gebruik**
- 2. Wat jy moet weet voordat jy Respiclear® Vapour Rub gebruik**
- 3. Hoe om Respiclear® Vapour Rub te gebruik**
- 4. Moontlike nuwe-effekte**
- 5. Bergingsaanwysings vir Respiclear® Vapour Rub**
- 6. Inhoud van die houër en ander belangrike inligting**

## **1. WAT IS RESPICLEAR® VAPOUR RUB EN WAARVOOR WORD DIT GEBRUIK:**

Respiclear® Vapour Rub word gebruik vir die verligting van verkoue- en griepsimptome. Respiclear® Vapour Rub bevat 'n mengsel van aromatiese essensiële olies waarvan die dampe asemhaling mag vergemaklik tydens kongestie.

## **2.WAT JY MOET WEET VOORDAT JY RESPICLEAR® VAPOUR RUB GEBRUIK**

Moenie Respiclear® Vapour Rub gebruik indien jy hipersensitief of allergies is vir enige van die gelyste bestanddele nie. Gebruik slegs soos voorgeskryf deur 'n dokter of apteker.

**Gebruik van ander medikasie saam met hierdie produk:** Raadpleeg jou dokter of geneesheer indien jy enige ander topikale preparate (insluitend tradisionele of komplimentêre produkte) op jou vel gebruik en graag Respiclear® Vapour Rub ook wil gebruik.

**Waarskuwing:** Vir medisinale gebruik. Slegs vir uitwendige gebruik. Vermy kontak met oë, ooglede, lippe en mukusmembrane. Indien kontak plaasvind, spoel die area deeglik af met water. Moenie Respiclear® Vapour Rub direk op die neusholtes aanwend in kinders jonger as 1 jaar nie aangesien gevalle van apnee en pulmonêre kollaps al gerapporteer is na topikale aanwending van mentol-olie. Staak onmiddellik die gebruik van hierdie produk indien enige ongewenste nuwe-effekte of irritasie voorkom. Nie vir die gebruik in kinders jonger as 6 maande nie.

## **3. HOE OM RESPICLEAR® VAPOUR RUB TE GEBRUIK**

Volwassenes: Smeer 'n redelike hoeveelheid aan die nek en bors, drie keer per dag. Twee spuite kan alternatiewelik in 500-ml warm (nie kokende) water gegooi word, en die dampe kan ingeasem word. Wees versigtig wanneer warm water gebruik word. Kinders ouer as 6 maande: Smeer een spuit versigtig aan die bors, veral voor slaaptijd. Gebruik spaarsamig op babas en jong kinders.

## **4.MOONTLIKE NEWE-EFFEKTE:**

Onbekend. Indien u algemene gesondheid vererger, of indien u enige nuwe- effekte ondervind tydens die gebruik van hierdie produk, raadpleeg u dokter, apteker of ander gesondheidswerker vir raad.

## **5.BERGINGSAANWYSINGS VIR RESPICLEAR® VAPOUR RUB**

Bewaar onder 30 °C in 'n koel, droë plek. Berg buite bereik van kinders. Moenie die produk gebruik na die vervaldatum op die ouer nie.

## **6. INHOUD VAN DIE HOUER EN ANDER BELANGRIKE INLIGTING**

Respiclear® Vapour Rub bevat per 1 gram:

Aktiewe bestanddele: Mentol-olie (*M. arvensis*) 35 mg, Kamfer-olie (*C. camphora*) 50 mg, Bloekomolie (*E. globulus*) 26 mg, Kaneelblaar-olie (*C. cassia*), Denne-olie (*P. palustris*) 14,5 mg. Onaktiewe bestanddele: Natrium benzoaat (0,15 %), Kalium sorbaat (0,15 %), EDTA<sub>2</sub>Na, Aqua (water), Butyrospermum parkii (Shea botter), Theobroma (kakao) saad botter, Polisorbaat 20P, groente gliserol, poliakriëlamied (en) C13-14 Iso-paraffien (en) C9-11 Pareth-6, en Xanthan gom.”

### **Aanbieding van Respiclear® Vapour Rub en inhoud van die houer**

Respiclear® Vapour Rub is naaswit room met 'n kenmerkende kruiereuk in 'n wit 50 ml pomp-botteltjie.

### **Naam en adres van die houer van die sertifikaat van registrasie**

Microbel Laboratories (Pty) Ltd, 86 Gazelle Ave, Corporate Park South, Midrand, Gauteng, 1685, Suid-Afrika.

Hierdie pamflet is laas hersien in November 2019.

Registrasie Nommer 422111 Act 101/1965

NAPPI kode 3000284001

Vir toegang tot die ooreenstemmende Professionele Inligting besoek: [www.obellabs.co.za](http://www.obellabs.co.za)