

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

Respiclear® (for inhalation)

Active substances: Eucalyptus oil (Eucalyptus globulus), Menthol (derived from Mentha arvensis), Camphor oil (Cinnamomum camphora), Pine (Pinus palustris) oil, White Thyme (Thymus vulgaris) oil.

Category D: Complementary Medicine, Aromatherapy 10.2.1 inhalants

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® drops are available without a doctor's prescription for you to treat congestion in bronchitis, colds and flu. Nevertheless, you still need to use Respiclear® drops carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Respiclear® drops 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® drops is and what it is used for**
- 2. What you need to know before you use Respiclear® drops**
- 3. How to use Respiclear® drops**
- 4. Possible side effects**
- 5. How to store Respiclear® drops**
- 6. Contents of the pack and other information**

1. WHAT RESPICLEAR® DROPS IS AND WHAT IT IS USED FOR

Respiclear® drops is used for the relief of congestion in bronchitis, colds and flu. Respiclear® drops 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® DROPS

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

Respiclear® drops is for external use only. Use only as directed by a medical practitioner or pharmacist. Avoid contact with the eyes, eyelids, lips, and mucous membranes. If accidental contact occurs, rinse area with water. Do not apply Respiclear® drops directly to the nostrils 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® DROPS

Adults and older children: For effective relief, squeeze 5-10 drops into 500 ml of hot water and inhale the vapor. Alternatively, apply 5-10 drops directly onto a tissue, pillow, or into a humidifier (only as directed by device manufacturer). Further doses may be used every 4 hours. Patients can also place 10 drops onto the corner of the shower floor, whilst having a hot shower, to find relief from cold & flu symptoms.

For young children and babies older than 6 months of age: Squeeze 5 drops onto a handkerchief tied down securely in the vicinity, but out of reach of the child.

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® DROPS

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® drops contains: Each 1 ml contains:

Active Ingredients: Eucalyptus oil (*Eucalyptus globulus*) 274 µL, Menthol (derived from *Mentha arvensis*) 157 µL, Camphor oil (*Cinnamomum camphora*) 313 µL, Pine (*Pinus palustris*) oil 156 µL, White Thyme (*Thymus vulgaris*) oil 78 µL. Inactive ingredients: Propylene Glycol 22 µL (propellant).

What Respiclear® drops looks like and contents of the pack:

Respiclear® drops is a clear to faintly yellow oil with a characteristic herbal odour in a clear PVC dropper bottle containing 10 ml. The bottle and Patient Information Leaflet are enclosed in a carton.

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.

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Access to the corresponding Professional Information: www.obellabs.co.za