

ReliHale

Read all of this leaflet carefully before you start using RELIHALE, because it contains important information for you. This medicine is available without a doctor's prescription. Nevertheless you still need to use RELIHALE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- You must see a doctor if your symptoms worsen or do not improve.
- Do not share RELIHALE with any other person.
- This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):

RELIHALE (Inhalant Capsules).

PHARMACOLOGICAL CLASSIFICATION:

D 32.2 Other. Complementary Medicine – Herbal Medicine.

WHAT RELIHALE CONTAINS:

Each soft gelatin capsule contains:

Ingredient	Quantity
Camphor USP	25 mg
Chlorothymol	5 mg
Eucalyptol USP	130 mg
Menthol USP	55 mg
Terpineol BP	110 mg
Preservatives	
Methyl paraben sodium	2,4 mg
Propyl paraben sodium	0,6 mg

Other inactive ingredients include Brilliant Blue FCF (CI42090), gelatin, glycerin, purified water, sorbitol 70 %, tartrazine yellow (CI19140).

WHAT RELIHALE IS USED FOR:

RELIHALE inhalant capsules contain a combination of essential oils that have been shown to assist in clearing nasal passages and providing relief from a blocked nose. RELIHALE is suitable for use in babies older than 3 months, children and adults.

BEFORE YOU USE RELIHALE:

Do NOT use RELIHALE:

- If you are allergic (hypersensitive) to any of the active or inactive ingredients in the formulation.
- If you are pregnant or breastfeeding your baby (see "**Pregnancy and breastfeeding**").
- **For children under 3 months of age.**

Take special care with RELIHALE:

- If you have kidney stones (renal calculi), as eucalyptol is contraindicated in this condition. Patients with kidney stones should avoid using RELIHALE.
- If you suffer from seizures, as menthol is contraindicated in these conditions. Patients suffering from seizures should avoid using RELIHALE.
- If you are scheduled for surgery, RELIHALE should be discontinued at least two weeks before surgical procedures. Remember to inform your doctor or anaesthetist that you are using RELIHALE.

Consult your doctor prior to using RELIHALE if any of the above precautions are applicable to you.

RELIHALE should not be used to replace any medicines prescribed by your doctor.

Consult your doctor if you are taking prescription medicines (see "**Using RELIHALE with other medicines**").

Pregnancy and breastfeeding:

Do NOT use RELIHALE while you are pregnant or breastfeeding your baby as safety has not been established (see "**Do NOT use RELIHALE** ").

If you are pregnant or breastfeeding your baby while using RELIHALE, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving or using machinery:

It is unlikely that RELIHALE will affect your ability to drive or operate machinery.

Using RELIHALE with other medicines:

As with any medicine, please contact your doctor, pharmacist or other healthcare professional before using RELIHALE in combination with any of the following medicines or substances:

- Alcohol containing medicines, as menthol may interact with these medicines.
- Hepatotoxic medicines, because the use of camphor may increase liver enzymes. These medicines include, but are not limited to, acarbose, amiodarone, azathioprine, carbamazepine, diclofenac, statins and valproic acid.

HOW TO USE RELIHALE:

To open the **RELIHALE** inhalation capsule, carefully snip off the tip of the capsule. Squeeze out the contents of the capsule into half a litre (500 ml) of boiling or hot water. Inhale the vapours deeply.

Alternatively add onto a tissue or handkerchief and inhale the vapours.

At night **RELIHALE** can be effectively applied onto the pillow or nightclothes.

Children older than 3 months: Apply the contents of the inhalation capsule onto a handkerchief or bedding. Tie the handkerchief firmly within the surrounding area, but out of reach of the child.

Consult your doctor if symptoms persist or return after the use of **RELIHALE**.

PRECAUTIONS:

Avoid direct contact with eyes and nostrils.

Use with caution in patients with skin infections or any drug allergy.

FOR EXTERNAL USE ONLY.

If you have the impression that the effect of **RELIHALE** is too strong or too weak, please speak to your doctor or pharmacist.

If you use more RELIHALE than you should:

If you use more **RELIHALE** than you should, you may experience an increase in the side-effects listed below (see “**POSSIBLE SIDE-EFFECTS**”).

- Inhalation of high concentrations vapour may cause irritation, respiratory and central nervous system (CNS) depression.
- Swallowing of the inhalation capsules may cause burning of the mouth and throat, nausea, vomiting, stomach pain, diarrhoea and sweating.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

POSSIBLE SIDE-EFFECTS:

RELIHALE may have side-effects.

Not all side-effects reported for RELIHALE are included in this leaflet. Should your general health worsen while using RELIHALE, please consult your doctor, pharmacist or other healthcare professional for advice.

Consult your doctor, pharmacist or healthcare professional if you experience any of the following signs and symptoms.

- Allergic (hypersensitive) reactions, including skin rash.
- Camphor: Inhalation may irritate the nose and throat (mucous membranes). Respiratory depression and apnoea may occur.
- Terpineol: Inhalation, at high concentrations, may cause central nervous system (CNS) depression.
- Menthol: Local application of menthol to nostrils, especially in infants, may cause apnoea and instant collapse.
- Chlorothymol: May irritate the stomach, if swallowed.

Please inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF RELIHALE:

Store at or below 25 °C.

Protect from light and moisture.

Keep the blisters in the outer carton until required for use.

Do not use the inhalation capsules after the expiry date stated on the package.

Return all unused capsules to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF RELIHALE:

Blister pack of 10 capsules packed in an outer carton.

IDENTIFICATION OF RELIHALE:

A green coloured ampoule shaped, soft gelatin capsule containing a colourless liquid.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Trinity Pharma (Pty) Ltd
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