Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Camphor, Chlorothymol, Eucalyptol, Menthol, Terpineol Inhalant Capsules
(Brand Name: KOLQ® Inhalant Capsules)

2. Qualitative and Quantitative Composition

Each Soft Gelatin Capsule Contains:
Camphor USP ……. 25 mg
Chlorothymol ……..... 5 mg
Eucalyptol USP ……..... 125 mg
Menthol IP ……..... 65 mg
Terpineol BP ……. 120 mg
Excipients …… q.s.
Colours used in capsule shell: Brilliant Blue & Tartrazine, Sodium Methyl paraben and Sodium Propyl Paraben used as Antimicrobial preservatives.

3. Dosage Form and Strength

Dosage Form: Soft gelatin capsule (for inhalation purpose).
Dosage Strength: Camphor 25 mg, Chlorothymol 5 mg, Eucalyptol 125 mg, Menthol 65 mg, Terpineol 120 mg per capsule.

4. Clinical Particulars

4.1Therapeutic Indication

KOLQ Inhalant Capsules are indicated for prompt relief from multiple symptoms due to common cold or allergic rhinitis such as runny nose, blocked nose (congestion), irritated nose, sore throat, sinus pain, headache and feelings of pressure and heavy-headedness.

4.2 Posology and Method of Administration

To be administered only by inhalation in adults and children above 6 years of age.
Usual Dosage: The KOLQ Inhalant Capsules can be inhaled up to 3 times daily.
Direction for Use: Snip off the tip of capsule. Squeeze out contents into half-litre of boiling or hot water or on a tissue or cloth handkerchief and inhale vapours deeply and freely.
At night the inhalation action can be obtained by squeezing out the capsule contents on the pillow or night dress.
Or, as prescribed by the physician.

4.3 Contraindications

KOLQ Inhalant Capsules are contraindicated in the following:

- Patients with known hypersensitivity to camphor, chlorothymol, eucalyptol, menthol, terpineol or to any other component of the formulation.
- Neonates.
- Epileptic patients.
- Children who have a history of febrile convulsions.

4.4 Special Warnings and Precautions for Use

- Avoid direct contact with eyes, nostrils, and skin. In case of exposure, rinse/wash the area thoroughly with cold water.
- Capsules must not be swallowed or taken internally.
- Capsules are for external / inhalation use only.
- In case of an allergic reaction, discontinue use of this product and seek medical help immediately.
- Avoid exposure to flame or do not keep near heat or microwave.

4.5 Drug Interactions

KOLQ Inhalants Capsules are unlikely to cause any drug interactions.

4.6 Use in Special Populations

Pregnant Women

This formulation is not known to cause any problems during pregnancy. There are no adequate and well controlled studies for use of this formulation during pregnancy. Therefore, KOLQ Inhalant Capsules should be used only when clearly needed and under medical supervision.

Lactating Women

As this formulation is for inhalation use only, components of this medicine are unlikely to secrete in human milk. Breastfeeding women should use this medicine with caution and only when clearly needed.

Paediatric Patients

KOLQ Inhalant Capsules are indicated in children above 6 years of age. Due to lack of safety data, KOLQ Inhalant Capsules are not recommended for use in children below 6 years of age.

Geriatric Patients

Generally, dose adjustment is not required in the geriatric population. Elderly patients may be given the same dose as recommended for adults.

4.7 Effect on Ability to Drive and Use Machines

KOLQ Inhalant Capsules are not expected to have any influence on the ability to drive and use machines.

4.8 Undesirable Effects

KOLQ Inhalant Capsules are relatively safe and there are no known side effects.

Misuse: Accidental swallowing of the inhalational capsules might cause gastrointestinal symptoms like vomiting and diarrhoea. In such case, seek medical assistance and if necessary, the patient should be treated symptomatically.

4.9 Overdose

When used appropriately, no overdose has been reported with this product. In case of overdose, discontinue medication, treat patients symptomatically and institute supportive measures as required.

Misuse: Following oral ingestion, symptoms of overdose may include colic, dizziness, delirium, muscle twitching, epileptiform convulsions and depression of the central nervous system. Breathing may be difficult. There may also be haematuria and albuminuria.

After significant accidental consumption, acute poisoning might occur with nausea, vomiting, abdominal pain, headache, vertigo, feeling hot / flushing, convulsions, respiratory depression and coma.

Patients with severe gastrointestinal or neurological symptoms of poisoning should be observed and treated symptomatically. Do not induce vomiting. Convulsions may be controlled by the intravenous administration of diazepam 5 to 10 mg.

5. Pharmacological Properties

5.1 Mechanism of Action

KOLQ Inhalant Capsules produces nasal decongestant effect after inhalation of vapours. It is made from 5 different essential oils which acts locally and unblock the nose. Volatile/essential oil is a concentrated hydrophobic liquid containing volatile aromatic compounds from plants. This medication is generally used to treat symptoms of nasal congestions or relieving the symptoms of head colds and bronchitis. Eucalyptus oil, camphor, menthol, terpineol are volatile substances which produce an irritant effect on the respiratory tract, probably via a nasal/pulmonary arc, thus, provides relief from nasal congestion.

5.2 Pharmacodynamic Properties

Camphor

Camphor vapours ease nasal congestion. Camphor can also reduce the urge to cough.

Chlorothymol
Chlorothymol is a multipurpose phenolic antiseptic / oral disinfectant. It is useful in symptomatic relief from common cold.

Eucalyptol
Eucalyptol is often used as an inhalational agent with other volatile substances in mouth and throat disorders. Eucalyptol kills bacteria and eases breathing difficulties in conditions such as croup, asthma and bronchitis.

Menthol
Menthol is primarily used to relieve symptoms of bronchitis, sinusitis and similar conditions. Menthol is commonly used with camphor and eucalyptus oil for relieving nasal congestion.

Terpineol
Terpineol has antibacterial, antiviral, and immune system stimulant properties.

5.3 Pharmacokinetics Properties
This product exerts its action locally; little or no absorption is expected to occur.

6. Nonclinical Properties
6.1 Animal Toxicology
Camphor
Camphor appears to have moderate acute oral toxicity, with an LD50 of 1310 mg/kg in mice. It demonstrated moderate to high toxicity in acute inhalation studies (450 mg/m^3 (72 ppm) in mice and 500 mg/m^3 (80 ppm) in rats). In sub-chronic studies, inhaled camphor resulted in emphysema in mice at 210 mg/m^3 (33 ppm) and rabbits at 33 mg/m^3 (5 ppm). In 13-week sub-chronic dermal studies, camphor had no observed adverse effect levels (NOAELs) of 1000 mg/kg/day in mice and 250 mg/kg/day in rats. Negative results were reported in carcinogenicity tests for camphor. In addition, camphor was negative for genotoxicity in a microsome mutagenesis test, and a peripheral blood micronucleus assay. In developmental toxicity studies, camphor demonstrated no fetal toxicity (with NOAELs ≥ 800 mg/kg/day in rats) at dose levels that resulted in maternal toxicity.

Chlorothymol
LD50 values reported for chlorothymol in mouse by subcutaneous route was 2460 mg/kg. Chlorothymol was non-mutagenic in the paper-disk method using *E. coli*.

Eucalyptol
Acute toxicity: The acute oral LD50 value reported in rats was 2480 mg/kg. In rats, a lethal dose caused rapid cyanosis and stupor accompanied by irregular breathing, extreme sensitivity to

noise, convulsions, and death from respiratory failure. Single subcutaneous doses of 250 or 500 mg/kg increased the activity of drug metabolizing enzymes and stimulated bile flow. An increase in liver enzyme activity was also found in mice given 500 mg/kg orally.
Subacute toxicity: Groups of 6 male and 6 female Fischer 344 rats received eucalyptol for 28 days either by stomach tube on 5 days/week at doses of 150, 300, 600 and 1200 mg/kg or in encapsulated form with the diet at concentrations of 3750, 7500, 15000 and 30000 mg/kg, equivalent to 381 – 3342 mg/kg/day for the male rats and to 353 – 3516 mg/kg/day for the female rats. At dose levels of 600 mg/kg and higher, dose-related decrease of body weight gain and absence of a normal degree of hepatic centrilobular cytoplasmic vacuolization was observed in male rats. In addition, other dose-related lesions in the liver, kidneys and parotid salivary glands were found at all dose levels in male rats fed encapsulated eucalyptol.
Chronic toxicity/carcinogenicity: Groups of 52 male mice were given 0, 8 and 32 mg eucalyptol/kg/day in 1 ml toothpaste base/kg/day by gavage 6 days/week for 80 weeks followed by an observation period between 16 and 24 weeks according to the number of survivors. No treatment-related effects on body weight, food consumption, survival, weight of adrenals, kidneys, liver, lungs or spleen, on the microscopic appearance of brain, lungs, liver and kidneys and on the tumour incidence were observed.
Genotoxicity: Eucalyptol did not show mutagenic effects in the following strains of *Salmonella typhimurium* with or without metabolic activation: TA 98, TA 100, TA 1535 and TA 1537, and TA 97a, TA 98, TA 100 and TA 102.

Menthol

Menthol show low acute oral toxicity with LD50 values normally greater than 2000 mg/kg (rats and mice). Only limited studies are available investigating dermal toxicity. In one study the LD50 of menthol in rabbits was above 5000 mg/kg body weight. In a second investigation a dermal dose of 34500 mg menthol liquid per kg was lethal to a mouse.
Menthol was not mutagenic in the Ames test with the standard tester strains *Salmonella typhimurium* TA 92, TA 94, TA 98, TA 100, TA 1535, TA 1537, TA 2637 with and without metabolic activation and including cytotoxic concentrations.
Menthol was tested in a well performed study for carcinogenicity (103 weeks) in doses of 3750 and 7500 ppm in the feed in F344 rats and of 2000 and 4000 ppm in the feed in B6C3F1 mice. In male and female rats the survival rate was not affected by treatment and no carcinogenic effects of menthol were found in any organ.
There is no evidence indicating a potential of menthol to interfere adversely with reproduction. Histopathological examinations of the reproduction organs of rats and mice showed no changes in repeated dose toxicity studies with menthol and also in carcinogenicity studies with menthol.

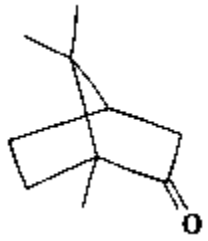
Terpineol

Oral LD50 value reported in rat and mouse were 4300 mg/kg and 2830 mg/kg respectively. LD50 value reported in mouse by intramuscular route was 2 gm/kg. LD50 value reported in mouse by subcutaneous route was 1360 mg/kg.
Following acute oral exposure, a low toxicity was generally reported in rodents. No indication of lung carcinogenicity was seen in a limited study in mice (treated by injection). Terpineol caused a slight but dose-related increase in the number of his+ revertants with *Salmonella* TA102 tester strain both without and with activation. The effects of terpineol on the compound action potential (CAP) of rat sciatic nerve were studied. Terpineol induced a dose-dependent blockade of the CAP.

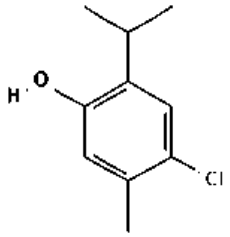
7. Description

KOLQ inhalant Capsules are Green transparent one end pointed soft gelatin capsules containing clear liquid.
Each inhalant capsule contains camphor 25 mg, chlorothymol 5 mg, eucalyptol 125 mg, menthol 65 mg, and terpineol 120 mg.

Camphor
Camphor appears as a colorless or white colored crystalline powder with a strong mothball-like odor.
Molecular Weight: 152.23g/mol.
Molecular Formula: C10H16O.
Chemical Name: 1,7,7-trimethylbicyclo[2.2.1]heptan-2-one.
Structural Formula:

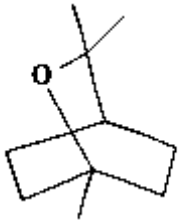


Chlorothymol
Chlorothymol appears as white coloured solid crystals.
Molecular Weight: 184.66 g/mol.
Molecular Formula: C10H13ClO.
Chemical Name: 4-chloro-5-methyl-2-propan-2-ylphenol.
Structural Name:



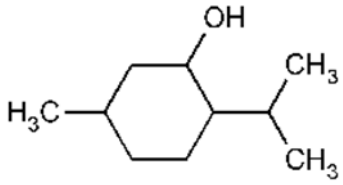
Eucalyptol

Eucalyptol is a colorless liquid with a camphor-like odor and spicy cooling taste.
Molecular Weight: 154.25g/mol.
Molecular Formula: C10H18O.
Chemical Name: 1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane.
Structural Formula:



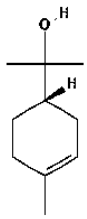
Menthol

Menthol is a white crystalline solid with a peppermint odor and taste.
Chemical Name: Cyclohexanol, 5-methyl-2-(1-methylethyl).
Molecular Weight: 156.27 g/mol
Molecular Formula: C10H20O.
Structural Formula:



Terpineol

Terpineol is a colourless, viscous liquid with a lilac-like odour.
Molecular Weight: 154.25 g/mol.
Molecular Formula: C10H18O.
Chemical Name: 2-[(1S)-4-methylcyclohex-3-en-1-yl]propan-2-ol.
Structural Formula:



Inactive ingredients (excipients) of KOLQ Inhalant Capsule contains Gelatin, Glycerin, Sorbitol Solution – 70 %, Sodium Methyl Paraben, Sodium Propyl Paraben, Colour Brilliant Blue FCF & Colour Tartrazine

8. Pharmaceutical Particulars

8.1 Incompatibilities

None known.

8.2 Shelf-life

24 months.

8.3 Packaging Information

10 inhalant capsules per Blister.

8.4 Storage and Handling Instructions

Store in a dry & dark place, at temperature not exceeding 25°C.
Keep out of reach of children.

9. Patient Counseling Information

Administration Instructions

Instruct patients:

- To avoid direct contact with eyes, nostrils, and skin. In case of exposure, rinse/wash the area thoroughly with cold water.
- To use this product (capsules) only for inhalation purpose and must not be swallowed or taken internally.
- To avoid exposure to flame and not to keep product near heat or microwave.
- Not to use this product in children below 6 years of age.

10.Details of Manufacturer

Pure & Cure Healthcare Pvt. Ltd.
(A subsidiary of Akums Drugs and Pharmaceuticals Ltd.,)

Plot No. 26 A, 27-30, Sector-6A, IIE, SIDCUL, Haridwar - 249 403, Uttarakhand.

11.Details of Permission or License Number with Date

Mfg. Lic. No. : 31/UA/2013. Date of FDA Product Permission: 07/11/2014.

12. Date of Revision

January 2021.

Marketed by:

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