PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Covonia Vapour Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Covonia Vapour Drops contains the following active ingredients:

Menthol natural or Menthol synthetic 17.5% w/v
Peppermint Oil 0.2% v/v

Excipients of known effect
Benzyl Alcohol 0.5% v/v
Ethanol 57% v/v

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Inhalation vapour, solution.

A clear yellow liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of catarrh, hay fever and nasal congestion.

4.2 Posology and method of administration

Adults, the elderly and children over 2 years:
Sprinkle a few drops on a handkerchief and inhale the vapour but avoiding direct skin contact.

4.3 Contraindications

Hypersensitivity to menthol, peppermint oil or any of the ingredients.

Children under 2 years of age.

4.4 Special warnings and precautions for use

The label states:

1 If symptoms persist, consult your doctor.

2 Avoid contact with the eyes and direct contact with the skin.

3 Do not place directly into the nostrils.

4 Not to be taken internally.

5 Keep out of the sight and reach of children.

Ingredients with specified warnings
This medicine contains 69mg of alcohol (ethanol) per 3 droplets. The amount in 3 droplets of this medicine is equivalent to less than 2ml of beer or 1ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.
This medicine contains 0.5% v/v benzyl alcohol per dose. Benzyl alcohol may cause allergic reactions.

4.5 Interactions with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

The safety of Covonia Vapour Drops in pregnancy and lactation has not been established, but as a precautionary measure it is preferable to avoid the use of Covonia Vapour Drops during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Occasional hypersensitivity reactions are a possibility for menthol (contact dermatitis) and peppermint oil (local irritation).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

Following oral ingestion, the following symptoms may be expected: insomnia, ataxia (unsteady gait, tremor of hands, vertigo, muscle twitching), severe abdominal pain, nausea and vomiting, burning in the mouth and throat, delirium, headache, dizziness, drowsiness, bradycardia, cyanosis, miosis, pulmonary damage, epileptiform convulsions, CNS depression and coma. Inhalation of large doses of menthol may lead to dizziness, confusion, muscle weakness, nausea and double vision.

Treatment should consist of gastric lavage and aspiration. A saline purgative such as 30g of sodium sulphate in 250ml of water may be given and any convulsions controlled by intravenous diazepam.

5.1 Pharmacodynamic properties

R0lA X - Other nasal preparations, combinations

Menthol, a frequent constituent of inhalation preparations, produces a sensation of decreased nasal congestion, possibly by virtue of its local anaesthetic action on the nasal mucosal surface. Peppermint Oil possesses the physiological actions and therapeutic uses of menthol.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

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6.1 List of excipients

Eucalyptus Oil
Cajuput Oil (Contains Benzyl Alcohol E1519)
Spike Lavender Fragrance Oil
Industrial Methylated Spirit (Contains Ethanol)

6.2 Incompatibilities

None stated.

6.3 Shelf Life

36 months

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

10ml (7.5ml fill), 15ml, 30ml - Amber glass bottle with polyethylene screw cap with integral polyethylene dropper.

6.6 Instructions for use, handling and disposal

Not applicable.

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00240/0073

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th June 2002

10 DATE OF REVISION OF THE TEXT

03/09/2020