1.3 South African labelling and packaging

1.3.1 South African Package Insert

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Applicant: Zimbili Pharma CC
Product Name: Karvol Decongestant Inhalation Capsules
Dosage form and strength: Menthol 35,55 mg; Chlorbutol 2,25 mg;
Thymol 3,15 mg; Total Pine Oil 112,05 mg;
Terpineol 66,60 mg and Cinnamon Oil 12,15 mg per capsule

APPROVED PACKAGED INSERT:

1. Scheduling status

S0

2. Proprietary name and dosage form

Karvol Decongestant Inhalation capsules

3. Composition Per Decongestant Capsule:

Menthol 35,55 mg

Chlorbutol 2,25 mg

Thymol 3,15 mg

Total Pine Oil 112,05 mg

Terpineol 66,60 mg

Cinnamon Oil 12,15 mg

Excipients: Cithrol 10 MS, polyethylene glycol 400, polysorbate 80 and triacetin.

4. Pharmacological classification

A/10.2.1/ Medicines acting on respiratory system. Inhalants.

5. Pharmacological action

The aromatic vapours of the active agents have decongestant action on the upper respiratory tract, giving symptomatic relief in nasal congestion, coryza and bronchitis.

6. Indications

For symptomatic relief in nasal congestion, coryza (head colds) and bronchitis.

7. Contraindications

Not recommended for children under 3 months of age.

8. Warnings and special precautions

There have been reports of apnoea and instant collapse in infants following the local application of menthol to their nostrils. Avoid contacts with eyes. Not to be applied directly to the nostrils. Hypersensitivity reactions to the individual ingredients could occur.

FOR EXTERNAL USE ONLY

9. Interactions

None known

10. Pregnancy and lactation

If you fall pregnant whilst on this medication, immediately consult your doctor, pharmacist or other healthcare professional.

11. Dosage and directions for use



Adults and older children:

Snip off the tip of one or two capsules. Squeeze the contents into 500 ml of hot water or onto a tissue and inhale the vapour. At night the inhalant can be effectively used on the bedding or in a humidifier. Consult your doctor symptoms persist.

Young children and babies older than 3 months:

Dab the contents of a CAPSULE onto a handkerchief tied down securely in the vicinity, but out of reach of the child. Karvol may be used in a humidifier.

12. Side effects

Hypersensitivity reactions to the individual ingredients could occur.

13 Known symptoms of over dosage and particulars of its treatment

An overdose by inhaling is treated by taking the patients into fresh air. Accidental intake by mouth may cause diarrhoea, stomach pain, nausea, vomiting and sweating.

Treatment: Empty stomach by aspiration an lavage (sucking out and washing). When large quantities are swallowed, hypotension (low blood pressure), dyspnoea (shortness of breath) and respiratory failure may occur. The respiration (breathing) should be assisted until spontaneous breathing is fully resorted.

14. Identification

Faintly yellow oil, with a characteristic odour in a clear, golden, soft gelatin flask shaped capsule with snip-off tip.

15. Presentation

PVC/PVDC blister foil containing 10 or 20 capsules placed in an outer carton.

16. Storage instructions

Store at or below 25 ˚C in a dry place.

KEEP OUT OF REACH OF CHILDREN.

17. Registration Number

G.777 (Act 101/1965)

18. Name and business address of the holder of the certificate of registration

Zimbili Pharma CC

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19. Date of publication of the package insert

March 2013