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

1.3 South African labelling and packaging

1.3.2 Patient Information Leaflet

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PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Karvol Decongestant Inhalation Capsules

Read all of this leaflet carefully because it contains important information for you

Karvol Decongestant Inhalation Capsules is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Karvol Decongestant Inhalation Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Karvol Decongestant Inhalation Capsules with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

1. WHAT *KARVOL DECONGESTANT INHALATION CAPSULES* CONTAINS:

The active ingredients are:

- 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

The other ingredients are:

- Cithrol 10 MS
- Polyethylene Glycol 400
- Polysorbate 80
- Triacetin

2. WHAT *KARVOL DECONGESTANT INHALATION CAPSULES* IS USED FOR:

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

3. BEFORE YOU TAKE *KARVOL DECONGESTANT INHALATION CAPSULES*

Do not take Karvol if you are hypersensitive (allergic) to any of the active substances or any of the other ingredients of Karvol.

Avoid contacts with eyes. Not to be applied directly to the nostrils. Hypersensitivity reactions to the individual ingredients could occur.

FOR EXTERNAL USE ONLY

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

4. HOW TO USE *KARVOL DECONGESTANT INHALATION CAPSULES:*

Always use *KARVOL DECONGESTANT INHALATION CAPSULES* as your doctor has instructed

you. You should check with your doctor or pharmacist if you are unsure. The actual dose is:



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

IF YOU TAKE MORE *KARVOL DECONGESTANT INHALATION CAPSULES* THAN YOU SHOULD:

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

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.

5. POSSIBLE SIDE EFFECTS

Hypersensitivity reactions to the individual ingredients could occur.

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

6. STORING AND DISPOSING OF *KARVOL DECONGESTANT INHALATION CAPSULES:*

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

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF *KARVOL DECONGESTANT INHALATION CAPSULES*:

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

8. IDENTIFICATION *OF KARVOL DECONGESTANT INHALATION CAPSULES*

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

9. REGISTRATION NUMBER/REFERENCE NUMBER:

G.777 (Act 101/1965)

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Zimbili Pharma CC

24 Parrot Avenue

Extension 1

Lenasia

1827

RSA

11. DATE OF PUBLICATION:

March 2013