1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

AURONE FORTE (ear drop)

COMPOSITION

Each 15 ml of AURONE FORTE contains:

Phenazone	750,00 mg
Benzocaine	150,00 mg
Chlorbutol	150,00 mg

Excipients:

Glycerol

CATEGORY AND CLASS

A 16.2 Aural preparations

PHARMACOLOGICAL ACTION

AURONE FORTE ear drop combines the antibacterial and antifungal properties of chlorbutol with the local anaesthetic properties of phenazone and benzocaine.

INDICATIONS

For the treatment of acute otitis media, simple catarrhal otitis, furunculosis and other inflammatory conditions and infections of the ear.

CONTRAINDICATIONS

Sensitivity to any of the ingredients. The administration of phenazone is contraindicated where there is a family history of porphyria.

WARNINGS AND SPECIAL PRECAUTIONS

Should not be used in conditions with ear discharge or perforated tympanic membrane.

The application of local anaesthetics to the skin for prolonged periods or to extensive areas should be avoided.

Local anaesthetics should be given cautiously to patients with epilepsy, impaired cardiac conduction, shock, myasthenia gravis or with liver damage.

Effects on ability to drive and use machines

Not known.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

5 to 10 drops, warmed to body temperature, to be instilled into the ear every two hours and the ear lightly plugged with cotton wool.

SIDE EFFECTS

Phenazone may give rise to skin eruptions in susceptible individuals. Benzocaine may cause methaemoglobinaemia.

Allergic reactions may appear.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Acute poisoning with chlorbutol may produce central nervous system depression with weakness, loss of consciousness and depressed respiration. The systemic toxicity of local anaesthetics mainly involves the central nervous system and the cardiovascular system. Excitation of the CNS may be manifested by restlessness, excitement, nervousness, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching and tremors, and convulsions. Numbness of the tongue and perioral region may appear as an early sign of systemic toxicity. Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma. Effects on the cardiovascular system may be myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia, arrhythmias and cardiac arrest. Treatment is symptomatic and supportive.

IDENTIFICATION

Thick, colourless to pale yellow liquid.

PRESENTATION

15 ml amber glass bottles with a round, flat topped, black polypropylene screw-on cap with a rubber teat and a glass pipette. The bottle is placed in an outer cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

H1390 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

Healthcare Park

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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