## 1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

### SCHEDULING STATUS

**S2**

### PROPRIETARY NAME AND DOSAGE FORM

**AURONE** (ear drops)

### COMPOSITION

Each 15 ml of AURONE contains:

Phenazone 750,00 mg

*Excipient:*

Glycerol

### CATEGORY AND CLASS

A 16.2 Aural preparations

### PHARMACOLOGICAL ACTION

**Pharmacodynamic properties**

AURONE contains phenazone which exhibits analgesic and anti-inflammatory properties similar to those of the salicylates.

### INDICATIONS

AURONE is used for the relief of painful inflammatory conditions of the ear.

## CONTRAINDICATIONS

Sensitivity to any of the ingredients.

The administration of AURONE 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.**

## INTERACTIONS

Not known.

## HUMAN REPRODUCTION

Not known.

## DOSAGE AND DIRECTIONS FOR USE

5 to10 drops, warmed to body temperature, to be instilled into the ear every two hours and the ear lightly plugged with cotton wool.

## SIDE EFFECTS

AURONE may give rise to skin eruptions in susceptible individuals.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

**Symptoms**

If AURONE is accidentally ingested, it may cause the following symptoms: nausea, headache, drowsiness, coma and convulsions.

**Treatment**

The stomach should be emptied by aspiration and lavage and a saline purgative should be administered.

**IDENTIFICATION**

A colourless to pale yellow viscous liquid.

**PRESENTATION**

15 ml is packed into amber glass bottle sealed with a round, flat topped black polypropylene screw-on cap with an expanded polyethylene liner together with a glass dropper with a rubber teat.

**STORAGE INSTRUCTIONS**

Store at or below 25 °C.

Keep container tightly closed.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

**REGISTRATION NUMBER**

H1389 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE APPLICANT**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

Date of registration: Old medicine

Date of the most recent amendment to the professional information as approved by the Authority: January 1975

| |
|---|
| Botswana: B9322090 S3 |

| |
|---|
| Namibia: NS1 14/16.2/0098 |

| |
|---|
| Zimbabwe: P. 90/20.1.2/2364 |

**ZA_AUROEDROP_7501_02**