

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

EarCalm Spray.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Acetic Acid (Glacial) Ph. Eur., 2.0% w/w

### **3 PHARMACEUTICAL FORM**

Ear spray for auricular use.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

EarCalm Spray is indicated for the treatment of superficial infections of the external auditory canal.

#### **4.2 Posology and method of administration**

Route of administration: Topical. For external aural use to the external auditory canal only.

Adults, children, aged 12 years and above, and the elderly.

For treatment of superficial infections of the outer ear: one metered dose (60 milligrams) to be administered directly into each affected ear at least three times daily (morning, evening and after swimming, showering or bathing). Maximum dosage frequency one spray every 2 - 3 hours.

Treatment should be continued until two days after symptoms have disappeared but no longer than 7 days.

Before using the product for the first time, prime the pump by depressing actuator 6 - 10 times until a fine spray is obtained. Use within 1 month of first actuation. If more than one week has elapsed since the last use, dispose of the contents of the pump chamber by 1 or 2 depressions of the actuator.

#### **4.3 Contraindications**

The product should not be used in patients with a known sensitivity to any of the ingredients.

Not recommended for children under 12 years of age without medical advice.

#### **4.4 Special warnings and precautions for use**

Do not use for more than 7 days. Avoid spraying near the eyes.

If pain occurs during use, or if symptoms worsen or do not improve within 48 hours, or if your hearing becomes impaired, stop treatment and consult your doctor.

Patients who are known to have a perforated ear drum should only use the product under medical supervision.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.6 Fertility, Pregnancy and lactation**

There are no known restrictions to the use of the product in pregnancy and lactation

#### **4.7 Effects on ability to drive and use machines**

Unresolved ear problems could themselves effect driving ability

#### **4.8 Undesirable effects**

Some patients may experience a transient stinging or burning sensation after dosing for the first few days of treatment.

##### **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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

Overdosage by this route is extremely unlikely.

If EarCalm should be accidentally swallowed, neutralisation with milk or water may be required.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Acetic acid possesses antibacterial activity. It is reported to be active against: Haemophilus and Pseudomonas species, Candida and Trichomonas.

## **5.2 Pharmacokinetic properties**

EarCalm Spray is applied topically to the external auditory meatus and acts locally.

## **5.3 Preclinical safety data**

Acetic acid is widely available and toxicity problems at this concentration are unlikely.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Macrogol (2) stearyl ether  
Macrogol (20) stearyl ether  
Stearyl alcohol  
Methyl parahydroxybenzoate  
Propyl parahydroxybenzoate  
Purified water

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

Shelf life of the product as packaged for sale: 24 months from the date of manufacture

Shelf life after first opening of the container: Use within one month of first use

## **6.4 Special precautions for storage**

Do not store above 25°C. Keep container upright in the outer carton.

## **6.5 Nature and contents of container**

5 ml of the product is supplied in a 8.5ml capacity amber glass bottle fitted with a spray device.

## **6.6 Special precautions for disposal and other handling**

Shake the bottle well before use. Before first use, press actuator down several times to obtain a fine spray. Each press then delivers one metered dose. Do not inhale the spray. Administer spray directly by gently placing nozzle tip into ear opening and pressing down once on the actuator.

Use within one month of first use. If there is a period of more than one week since last use, press actuator down a few times before using again.

**7      MARKETING AUTHORISATION HOLDER**

Teva UK Limited,  
Ridings Point, Whistler Drive,  
Castleford,  
WF10 5HX,  
United Kingdom

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00289/2300

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

21/05/2008

**10     DATE OF REVISION OF THE TEXT**

27/10/2021