

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

ACULAR 0.5% w/v Eye drops, solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 5 mg ketorolac trometamol.

Excipient with known effect

Each ml contains 0.1 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye drops, solution

*Product imported from France*

Clear, colourless to pale yellow aqueous solution.

## 4 CLINICAL PARTICULARS

As per PA1824/015/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1824/015/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium chloride

Benzalkonium chloride 50% solution

Sodium Edetate

Octoxinol

Sodium hydroxide 1N or hydrochloric acid 1N

Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

Use within 15 days of first opening.

### 6.4 Special precautions for storage

Store below 25 °C.

**6.5 Nature and contents of container**

5ml of solution in a dropper bottle (PE) with a screw cap.

**6.6 Special precautions for disposal**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/287/001

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

Date of first authorisation: 20th July 2012

**10 DATE OF REVISION OF THE TEXT**

February 2026