

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

ACULAR 0.5% w/v Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketorolac trometamol 5 mg/ml.

Excipients: Benzalkonium chloride

For a 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 PA0148/057/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0148/057/001

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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

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

May 2015