

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.

Excipient(s) with known effect: 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 PA1824/015/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1824/015/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Benzalkonium chloride
Disodium Edetate
Octoxinol 40
Sodium hydroxide or hydrochloric acid (to adjust pH)
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 and other handling

No special requirements.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue,
Northwest Business Park,
Ballycoolin,
Dublin 15,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/200/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th January 2023

10 DATE OF REVISION OF THE TEXT