

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 0.01mg/ml

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution

Product imported from the UK:

Clear, colourless to pale yellow aqueous solution.

4 CLINICAL PARTICULARS

As per PA 148/057/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 148/057/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Disodium edetate

Octoxynol 40,

Sodium chloride

Sodium hydroxide or hydrochloric acid (to adjust pH)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Use within 28 days of first opening.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Bottle with dropper applicator, containing clear, colourless to slightly yellow, sterile ophthalmic solution. Pack size: 5ml.

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

LTT Pharma Limited
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Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/037/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2010

10 DATE OF REVISION OF THE TEXT

October 2014