

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 0.5% w/v.

Excipient(s) with known effect:

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 PA0148/057/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0148/057/001

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 is the date shown on the bottle and outer carton of the product as marketed 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

Overlabelled outer carton containing a plastic bottle.

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

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/142/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd of December 2010

10 DATE OF REVISION OF THE TEXT

March 2018