

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucithalamic 10mg/g Viscous Eye Drops, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains 1 % w/w fusidic acid.

Excipient with known effect: contains benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, suspension (eye drops)

Product imported from Greece:

A white to off-white viscous suspension.

4 CLINICAL PARTICULARS

As per PA 1142/016/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1142/016/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Disodium edetate

Mannitol

Carbomer

Sodium hydroxide (for pH adjustment)

Water for injections

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.

After first opening container: Discard any remaining drops one month after first opening.

6.4 Special precautions for storage

Do not store above 25°C. Keep cap tightly closed.

6.5 Nature and contents of container

Tube, with a cap, containing 5 g of eye drops suspension in a cardboard outer carton.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal 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
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/339/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th January 2015

10 DATE OF REVISION OF THE TEXT