

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zovirax 30 mg/g Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 30 mg aciclovir equivalent to 3 %w/w aciclovir.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye ointment

Product imported from Italy:

Soft, homogenous, white to off-white, slightly translucent, unctuous mass.

4 CLINICAL PARTICULARS

As per PA 1077/084/002

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/084/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White petrolatum.

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.

6.4 Special precautions for storage

Do not store above 25°C.

Discard one month after opening.

6.5 Nature and contents of container

White to pale yellow sterile ointment contained in a tube with a tamper evident screw cap.

Pack sizes 4.5g tube.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/333/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st February 2014

10 DATE OF REVISION OF THE TEXT

February 2016