

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zovirax 5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 50 mg (5 % w/w) aciclovir.

Excipients: Cetostearyl alcohol
Propylene glycol (E1520)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from Spain and the United Kingdom:

Smooth, odourless, white to off-white cream.

4 CLINICAL PARTICULARS

As per PA 1077/084/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/084/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Spain:

Cetostearyl alcohol
Sodium laurilsulfate
Poloxamer 407
Liquid paraffin
Propylene glycol (E1520)
White soft paraffin
Dimeticone 20
Arlacel 165
Purified water

Product imported from UK:

Cetostearyl alcohol
Sodium laurilsulfate
Poloxamer 407
Liquid paraffin
Propylene glycol (E1520)
White soft paraffin
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.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

Collapsible lacquered aluminium tube with plastic screw cap, crimped end and a membrane seal at the nozzle end. A spike is incorporated into the structure of the cap.

Over-labelled outer carton and over-labelled tube.

Pack size: 2g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th April 2007

Date of last renewal: 20th April 2012

10 DATE OF REVISION OF THE TEXT

November 2015