

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zovirax Cold Sore 5% w/w cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5% w/w aciclovir.

Excipients with known effect(s): Propylene glycol and cetostearyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from Spain

A smooth white to off-white cream.

4 CLINICAL PARTICULARS

As per PA0678/090/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0678/090/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Poloxamer 407
Cetostearyl alcohol
Sodium laurilsulfate
White soft paraffin
Liquid paraffin
Propylene glycol (E1520)
Purified water
Demeticone 20
Glycerol
Monostearate / Macrogol Stearate (Arlacel 165)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton of the product as marketed 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

Tube enclosed in a plastic bottle, which is enclosed in an outer cardboard container: Pack size: 2g or tube in an outer cardboard container: Pack size: 2g

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/038/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 December 2001

Date of last renewal: 14 December 2006

10 DATE OF REVISION OF THE TEXT

June 2021