

## 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: contains Propylene glycol, and cetostearyl alcohol

For a 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  
Purified water  
Dimeticone 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 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**

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

### **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**

October 2016