

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Zovirax 200 mg/5 mL oral suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oral suspension containing 200 mg aciclovir per 5 mL.

### Excipient(s) with known effect:

Sorbitol Liquid (non-crystallising)

Methyl parahydroxybenzoate

Propyl parahydroxybenzoate

Propylene glycol (E1520)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral suspension.

*Product imported from Germany*

Off-white, banana flavoured, suspension

## 4 CLINICAL PARTICULARS

As per PA1077/084/005

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/084/005

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sorbitol Liquid (non-crystallising) (E420)

Glycerol

Microcrystalline cellulose

Carmellose sodium

Vanillin

Banana flavour (contains propylene glycol (E1520))

Purified water

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

### 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 package of the product on the market in the country of origin.

Diluted: 4 weeks

#### **6.4 Special precautions for storage**

Do not store above 25°C.

#### **6.5 Nature and contents of container**

62.5 mL amber glass bottle with white, child resistant cap containing a homogenous opaque white, viscous suspension having the taste and odour of banana. The pack contains 2 x 62.5 mL bottles and a double ended 5 mL/2.5 mL spoon.

#### **6.6 Special precautions for disposal**

For administration of 100 mg dose e.g. 2.5 mL of Zovirax 200 mg/5 mL oral suspension, use the measuring spoon provided or alternatively a graduated syringe.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/038/008

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19<sup>th</sup> May 2017

### **10 DATE OF REVISION OF THE TEXT**

January 2026