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 parahydroxbenzoate
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: 19th May 2017

10 DATE OF REVISION OF THE TEXT

May 2021