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.

Excipients with known effect:
Sorbitol solution 70%
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)

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 solution-70%
glycerol,
microcrystalline cellulose and
carmellose sodium,
vanilllin,
banana flavour,
purified water,
methyl 4-hydroxybenzoate
propyl 4-hydroxybenzoate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.
Once opened use within 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

125mL (2x62.5 mL) amber glass bottles with white, child resistant cap containing a homogenous opaque white, viscous suspension having the taste and odour of banana. The pack contains a double ended 5 mL/2.5 mL spoon.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/183/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2016

10 DATE OF REVISION OF THE TEXT