Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Famvir 500mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 500 mg famciclovir.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product as placed on the market in Greece:
White, oval film-coated tablet, biconvex, bevelled edges, debossed with “FV 500” on one side and plain on the reverse side.

4 CLINICAL PARTICULARS

As per PA0013/106/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/106/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Hyprolose
Sodium Starch Glycollate
Magnesium Stearate

Tablet coat:
Hypromellose
Titanium Dioxide (E171)
Polyethylene glycol 4000
Polyethylene glycol 6000

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25ºC. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Famvir is supplied in Aluminium blister packs containing 21 tablets.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/212/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th July 2014

10 DATE OF REVISION OF THE TEXT

August 2015