

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Famvir 250mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet 250 mg of famciclovir.

Excipient with known effects:contains anhydrous lactose.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-Coated Tablet

Product imported from Greece and Italy:

White, round, film-coated, biconvex, bevelled edges, debossed with FV on one side and '250' on the reverse side.

4 CLINICAL PARTICULARS

As per PA0013/106/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0013/106/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxypropyl cellulose
Lactose anhydrous
Sodium starch glycollate
Magnesium stearate (E572)
Hypromellose
Titanium dioxide (E171)
Macrogol 4000
Macrogol 6000

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.

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister packs containing 21 tablets in an over-labelled outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/212/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th September 2008

10 DATE OF REVISION OF THE TEXT

June 2016