Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Famvir 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 500 mg of famciclovir.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from 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 PA1113/018/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1113/018/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Sodium starch glycolate (Type A) Hydroxypropylcellulose
Magnesium stearate

Tablet coat:
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 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 PVC/PVdC/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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/166/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 2021

10 DATE OF REVISION OF THE TEXT