

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Valtrex 500 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains valaciclovir hydrochloride equivalent to 500 mg valaciclovir

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from Greece.

500 mg tablet

White, biconvex, elongated tablet with a white to off-white core, engraved "GX CF1" on one side.

4 CLINICAL PARTICULARS

As per PA1077/082/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/082/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Microcrystalline cellulose

Crospovidone

Povidone

Magnesium stearate

Silicon dioxide anhydrous

Tablet coating:

Hypromellose

Titanium dioxide

Polyethylene glycol 400

Polysorbate 80

Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Blister pack of 10, 30 or 42 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th July 2020

10 DATE OF REVISION OF THE TEXT

October 2021