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 tablet

Product imported from Czech Republic
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
Silica colloidal anhydrous

Film coat
Hypromellose
Titanium dioxide
Macrogol 400
Polysorbate 80
Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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

Polyvinyl chloride / aluminium foil blister packs.
Packs of 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/459/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th December 2020

10 DATE OF REVISION OF THE TEXT

April 2023