

# 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: 18<sup>th</sup> December 2020

**10 DATE OF REVISION OF THE TEXT**