

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 container 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

PVC/AL blister packs.

Cartons containing 42 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
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Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/173/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th April 2021

10 DATE OF REVISION OF THE TEXT