

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Valcyte 450 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 496.3 mg of valganciclovir hydrochloride equivalent to 450 mg of valganciclovir (as free base). For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the United Kingdom, Italy and Poland:
Pink, convex, oval film-coated tablets with “VGC” embossed on one side and “450” on the other side.

4 CLINICAL PARTICULARS

As per PA0050/150/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0050/150/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core
Povidone K30
Crospovidone
Microcrystalline Cellulose
Stearic acid

Tablet Film-coat
Opadry Pink 15B24005 containing:
Hypromellose
Titanium dioxide (E171)
Macrogol 400
Red iron oxide (E172)
Polysorbate 80

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry for 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

High density polyethylene (HDPE) bottle, with child-resistant polypropylene closure, and cotton pad enclosed.
60 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

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/221/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th July 2009

10 DATE OF REVISION OF THE TEXT

August 2016