Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zovirax 800 mg Dispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dispersible tablet contains 800 mg aciclovir.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Dispersible tablets.

Product imported from Greece.

White, biconvex, elongated, film-coated tablet, impressed with 'GX CG1' on one face.

4 CLINICAL PARTICULARS

As per PA1077/084/009

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/084/009

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Aluminium magnesium silicate
Sodium starch glycollate
Povidone K30
Magnesium stearate
Hypromellose
Titanium dioxide (E171)
Polyethylene glycol 400
Polyethylene glycol 8000

6.2 Incompatibilities

There are no special requirements for use on handling of this product.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 30°C. Keep the blisters in the outer carton in order to protect from light and moisture.

6.5 Nature and contents of container

Each pack contains 35 dispersible tablets. 7dispersible tablets per child-resistant foil blister.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.,
Joop Geesinkweg 901,
1114 AB Amsterdam-Duivendrecht,
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 2024

10 DATE OF REVISION OF THE TEXT