# **Health Products Regulatory Authority**

# **Summary of Product Characteristics**

#### **1 NAME OF THE MEDICINAL PRODUCT**

Zovirax 800 mg Dispersible Tablets

# **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains 800mg aciclovir

For a full list of excipients, see section 6.1

#### **3 PHARMACEUTICAL FORM**

**Dispersible Tablets** 

Product imported from the UK White, oval tablets marked 'GXCG1' on one side.

#### **4 CLINICAL PARTICULARS**

As per PA 1077/084/009

# **5 PHARMACOLOGICAL PROPERTIES**

As per PA 1077/084/009

#### **6 PHARMACEUTICAL PARTICULARS**

# 6.1 List of excipients

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

# **6.2 Incompatibilities**

Not applicable.

#### 6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the blister and outer package of the product as marketed 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

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Outer carton containing blister strips

Pack size: 35

# 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. Unit 625 Kilshane Avenue Northwest Business Park Ballycoolin Dublin 15 Ireland

# **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/132/003

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20<sup>th</sup> December 2013

#### 10 DATE OF REVISION OF THE TEXT

April 2020

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