

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Teveten Plus 600 mg/12.5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains eprosartan mesylate equivalent to 600 mg eprosartan and 12.5 mg hydrochlorothiazide.

Excipient with known effect

Lactose (as monohydrate)

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Greece*

Butterscotch-coloured, capsule-shaped film-coated tablets

The inscription of the tablet is "5147" on one side.

## 4 CLINICAL PARTICULARS

As per PA2010/018/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA2010/018/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Tablet core:

Lactose monohydrate

Microcrystalline cellulose

Pregelatinised starch (from maize)

Crospovidone

Magnesium stearate

Purified water

#### Film coat:

Polyvinyl alcohol

Talc

Titanium dioxide (E171)

Macrogol 3350

Iron oxide yellow (E172)

Iron oxide black (E172)

### 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 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**

Blister packs of 28 tablets contained in an outer cardboard carton.

### **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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/448/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24<sup>th</sup> May 2019

## **10 DATE OF REVISION OF THE TEXT**