

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Serc 16 mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16 mg betahistine dihydrochloride, equivalent to 10.42 mg betahistine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet.

*Product imported from Spain:*

Round, biconvex, scored, white to almost white tablets imprinted '267' on one face.

The tablet can be divided into equal halves.

## 4 CLINICAL PARTICULARS

As per PA23355/014/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23355/014/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose

Mannitol (E421)

Citric acid monohydrate

Colloidal anhydrous silica

Talc

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product shall be 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 temperature storage conditions. Store in the original package.

### 6.5 Nature and contents of container

Blister strips of 15 tablets.

The blister strips are made of PVC/PVDC film with a covering aluminium foil.

Each carton contains 90 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**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/482/001

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

Date of first authorisation: 12<sup>th</sup> November 2021

**10 DATE OF REVISION OF THE TEXT**

January 2024