

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Serc 8mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8 mg betahistine dihydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from UK

A white to almost white, round, flat tablet, imprinted '256' on one face.

4 CLINICAL PARTICULARS

As per PA2010/016/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/016/001

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 container and outer package of the product on the market in the country of origin

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/026/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th February 2013

10 DATE OF REVISION OF THE TEXT

January 2019