

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seretide 100 Diskus, 50 microgram/100 microgram/dose inhalation powder, pre-dispensed.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-dispensed dose contains 50 micrograms salmeterol (as salmeterol xinafoate) and 100 micrograms fluticasone propionate.

Excipient(s) with known effect: lactose monohydrate
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed.

Product imported from the Greece, Poland & UK
Moulded plastic device containing a foil strip with 60 regularly placed blisters.

4 CLINICAL PARTICULARS

As per PA 1077/046/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/046/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (which contains milk proteins)

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 30°C.

6.5 Nature and contents of container

The inhalation powder is contained in a blister strip. The strip is contained in a moulded plastic purple device. The plastic device is available in an over-labelled cardboard container which holds 1 x 60 dose Diskus.

6.6 Special precautions for disposal and other handling

The Diskus releases a powder which is inhaled into the lungs.

A dose indicator on the Diskus indicates the number of doses left.

For detailed instructions for use refer to the package leaflet.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/006/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 25th June 2009

10 DATE OF REVISION OF THE TEXT

June 2018