Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose of Seretide provides:
50 micrograms of salmeterol (as salmeterol xinafoate) and 100 micrograms of fluticasone propionate.

Excipients: lactose monohydrate
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed.

Product imported from Poland and Romania:
A purple moulded plastic device containing a blister strip with individual doses of an inhalation powder.

4 CLINICAL PARTICULARS

As per PA1077/046/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/001

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 packaging 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 blisters held on a formed PVC coated base, with a peelable foil laminate lid. The strip is contained in a moulded plastic device.
The plastic devices are available in cardboard containers, which hold a 1 x 60 dose Diskus.

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

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 see the Patient Information Leaflet.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
157-173 Roden Street
Belfast
BT12 5QA
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/018/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th of May 2011

10 DATE OF REVISION OF THE TEXT

October 2014