Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seretide 500 Diskus 50 microgram/500 microgram/dose inhalation powder, pre-dispensed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single dose inhalation provides a delivered dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as salmeterol xinafoate) and 460 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 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 Poland and Czech Republic
Moulded plastic device containing a foil strip with 60 regularly placed blisters.

4 CLINICAL PARTICULARS

As per PA1077/046/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipient: 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 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 device is available in a 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 see the Patient Information Leaflet.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd January 2009

10 DATE OF REVISION OF THE TEXT

March 2023