

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Seretide 250 Diskus 50 microgram/250 microgram/dose inhalation powder, pre-dispensed

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-dispensed dose contains 50 micrograms salmeterol (as salmeterol xinafoate) and 250 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 Spain, Poland, Italy, Bulgaria and Romania*

Moulded plastic device containing a foil strip with 60 regularly placed blisters.

### 4 CLINICAL PARTICULARS

As per PA1077/046/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/002

### 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 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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/006/002

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

Date of First Authorisation: 23<sup>rd</sup> November 2007

## **10 DATE OF REVISION OF THE TEXT**

June 2018