# 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 of salmeterol (as salmeterol xinafoate) and 100 micrograms of fluticasone propionate.

Excipient 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 Bulgaria*

Inhalation device contains a strip covered with foil.

## 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

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the diskus 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

Seretide Diskus contains a strip covered with foil. Inhaler device is packed in a carton and contains 60 doses.

## 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

LTT Pharma Limited
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## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/141/003

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

Date of first authorisation: 7th October 2016

## 10 DATE OF REVISION OF THE TEXT

April 2017