

# 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 single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as salmeterol xinafoate) and 231 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms fluticasone propionate.

### Excipient with known effect

Each delivered dose contains up to 12.5 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed.

*Product imported from Greece, The Netherlands, Italy, Poland, France, Romania, Bulgaria & The Czech Republic*

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

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 purple 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 release 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**

PCO Manufacturing Ltd.  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/091/002

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

Date of first authorisation: January 2003

Date of last renewal: February 2015

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

August 2023