

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Seretide 50 Evohaler 25 microgram/50 microgram/dose pressurised inhalation, suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single actuation of Seretide provides:

25 micrograms of salmeterol (as salmeterol xinafoate) and 50 micrograms of fluticasone propionate (delivered from the valve). This is equivalent to 21 micrograms of salmeterol and 44 micrograms of fluticasone propionate delivered from the actuator (delivered dose).

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

*Product imported from Greece and the UK:*

The canister contains a white to off white suspension.

### 4 CLINICAL PARTICULARS

As per PA1077/046/004

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/004

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Norflurane (HFA 134a)

#### 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

Replace the mouthpiece cover firmly and snap it into position.

The canister contains a pressurised liquid.

Do not store above 25°C. Do not expose to temperatures higher than 50°C, protect from direct sunlight.

The container should not be punctured, broken or burnt even when apparently empty.

As with most inhaled medicinal products in pressurised containers, the therapeutic effect of this medicinal product may decrease when the container is cold.

## **6.5 Nature and contents of container**

The suspension is contained in an internally lacquered, 8ml aluminium alloy pressurised container sealed with a metering valve. The containers are fitted into plastic actuators incorporating an atomising mouthpiece and fitted with dustcaps. The canister has a counter attached to it, which shows how many actuations of medicine are left. The number will show through a window in the back of the plastic actuator. One pressurised container delivers 120 actuations.

The devices are available in cardboard containers, which hold:

1 x 120 actuations Inhaler

## **6.6 Special precautions for disposal and other handling**

No special requirements

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/091/004

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

Date of first authorisation: 6<sup>th</sup> February 2004

Date of last renewal: 6<sup>th</sup> February 2009

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

July 2016