Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seretide 125 Evohaler 25 microgram/125 microgram/dose pressurised inhalation, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single actuation of Seretide provides 25 micrograms of salmeterol (as salmeterol xinafoate) and 125 micrograms of fluticasone propionate. (delivered from the valve). This is equivalent to 21 micrograms of salmeterol and 110 micrograms of fluticasone propionate delivered from the actuator (delivered dose).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

Product imported from Belgium, Greece, Hungary and Poland:
The canister contains a white to off white suspension.

4 CLINICAL PARTICULARS

As per PA1077/046/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/005

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

Do not store above 25°C. Do not refrigerate or freeze.
The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C, protect from direct sunlight.
Do not puncture, pierce or burn the canister 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. 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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/091/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2004

Date of last renewal: 6th February 2009

10 DATE OF REVISION OF THE TEXT

August 2023