Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Seretide 250 Evohaler 25 microgram/250 microgram/dose pressurised inhalation, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose (ex valve) contains:
25 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate. This is equivalent to a delivered dose (ex actuator) of 21 micrograms of salmeterol and 220 micrograms of fluticasone propionate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from Belgium and Greece:
Pressurised inhalation, suspension.

The canister contains a white to off white suspension.
The canisters are fitted into purple plastic actuators incorporating an atomising orifice and fitted with dustcaps.

4 CLINICAL PARTICULARS

As per PA1077/046/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propellant: 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

An overlabelled outer container has enclosed the suspension contained in an internally lacquered, 8 ml 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 evohalers also have a counter attached to them, which shows how many actuations of medicine are left. The number will show through a window in the back of the plastic actuator.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/091/006

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

December 2022