

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 single actuation of Seretide provides:

25 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate (delivered from the valve). This is equivalent to 21 micrograms of salmeterol and 220 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 Italy:

The canister contains a white to off white suspension

4 CLINICAL PARTICULARS

As per PA1077/046/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/006

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 label and outer carton 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. The container should not be punctured, broken or burnt even when apparently empty.

As with most inhaled medical 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

Suspension in a pressurised metal canister sealed with a metering valve.

The canisters 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.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Clear Pharmacy
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Belfast BT12 5QA
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1596/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th of October 2010

10 DATE OF REVISION OF THE TEXT

October 2014