

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 metered dose (ex valve) contains:

25 micrograms of salmeterol (as salmeterol xinafoate) and 125 micrograms of fluticasone propionate. This is equivalent to a delivered dose (ex actuator) of 21 micrograms of salmeterol and 110 micrograms of fluticasone propionate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from Holland

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 PA1077/046/005

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/046/005

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 is the date shown on the container and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C, protect from direct sunlight. Do not pierce or burn the canister even when empty.

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

6.5 Nature and contents of container

The suspension is contained in an internally lacquered, 8mL aluminium alloy pressurised canister sealed with a metering valve. The canisters are fitted into purple 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 canister 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

IMED Healthcare Ltd
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/006/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st July 2016

10 DATE OF REVISION OF THE TEXT

February 2018