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

Pressurised inhalation, suspension.
Product imported from Austria, Romania, Italy & Spain
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 container and outer package of the product as marketed 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

A pressurised container sealed with a metering valve.

The container is fitted into a plastic actuator incorporating an atomising mouthpiece and fitted with a dustcap.
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.
Pack size: 1 x 120 actuations

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

Imbat Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/006/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th March 2011

10 DATE OF REVISION OF THE TEXT

August 2019