

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One metered dose (ex-valve) contains 25 micrograms salmeterol (as xinafoate). This is equivalent to a delivered dose (ex-actuator) of 21 micrograms salmeterol (as xinafoate).

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Pressurised inhalation suspension

*Product imported from Hungary.*

White to off white suspension sealed in an aluminium canister in a green actuator.

### 4 CLINICAL PARTICULARS

As per PA1077/047/005

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/047/005

### 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 for this product shall be the date shown on the device and outer package of the product on the market in the country of origin.

#### 6.4 Special precautions for storage

Do not store above 30° C.

Replace the mouthpiece cover firmly and snap it into position.

Pressurised container. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn even when apparently empty.

## **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.

## **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**

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
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## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/149/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 6<sup>th</sup> March 2015

## **10 DATE OF REVISION OF THE TEXT**