

# 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 Poland:*

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 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

Replace the mouthpiece cover firmly and snap it into position.

Do not store above 30° C.

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 a pressurised container sealed with a metering valve. The containers are fitted into plastic actuators a mouthpiece and fitted with dustcaps. One pressurised container delivers 120 actuations.

## **6.6 Special precautions for disposal**

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

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/503/001

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

Date of first authorisation: 5<sup>th</sup> January 2024

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