

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 a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension

Product imported from Hungary and Portugal:

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), a hydrofluoroalkane (non-chlorofluorocarbon) propellant

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 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 and other handling

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10
Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/127/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th April 2011

10 DATE OF REVISION OF THE TEXT

November 2014