

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ventolin Evohaler 100 micrograms Pressurised Inhalation, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 100 micrograms salbutamol (as sulfate).

For the full list of excipients, *see section 6.1*.

3 PHARMACEUTICAL FORM

Pressurised inhalation suspension.

Product imported from The Netherlands, Spain and The UK

Pressurised inhalation suspension supplied in an aluminium can with metering valve and a blue actuator.

4 CLINICAL PARTICULARS

As per PA 1077/049/010

5 PHARMACOLOGICAL PROPERTIES

As per PA 1077/049/010

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Norflurane (Hydrofluoroalkane (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

Do not store above 30°C. Do not refrigerate or freeze.

Protect from frost and sunlight.

Replace the mouthpiece cover firmly and snap into position.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C.

Do not pierce the container even when apparently empty.

6.5 Nature and contents of container

Pressurised, seamless aluminium canister fitted with a metered dose valve and accompanied by an inhalation adaptor for manual activation.

Each canister contains at least 200 metered doses.

6.6 Special precautions for disposal and other handling

Patients should be carefully instructed in the correct use of the inhaler.

No special requirements 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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 April 2001

Date of last renewal: 20 April 2006

10 DATE OF REVISION OF THE TEXT

March 2016