

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 of Salbutamol (as sulfate)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation suspension

Product imported from the UK

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

4 CLINICAL PARTICULARS

As per PA1077/049/010

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/049/010

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

HFA 134a

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is 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

Store below 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

The suspension is contained in an aluminium alloy can and sealed with a metering valve. Each canister is fitted into a plastic actuator and fitted with a dust cap. Each canister contains at least 200 metered doses.

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

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

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th April 2018

10 DATE OF REVISION OF THE TEXT