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 sulphate).
For a 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

Norflurane (Hydrofluoralkane (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

Store below 30°C. Do not refrigerate or freeze.
The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C.
Do not pierce the canister even when apparently empty.

6.5 Nature and contents of container

The suspension is contained in an aluminium alloy can, internally coated with fluoropolymer and sealed with a metering valve. Each canister is fitted into a plastic actuator incorporating an atomising nozzle and fitted with a dustcap. 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.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/041/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th August 2006

Date of last renewal: 18th August 2011

10 DATE OF REVISION OF THE TEXT

November 2015