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 a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pressurised inhalation suspension

Product imported from Greece and Romania:
Pressurised inhalation suspension supplied in an aluminium can with metering valve and a two tone blue plastic actuator and dustcap.

Product imported from The UK:
Pressurised inhalation suspension supplied in an aluminium can with metering valve and a two tone blue plastic actuator and dustcap. There is an embossed letter “V” on the plastic case and ridged touch pad.

4 CLINICAL PARTICULARS

As per PA1077/049/010

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/049/010

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Romania: Norflurane (1, 1, 1, 2 – Tetrafluoroethane, HFA 134a)
Greece: Norflurane (Hydrofluoralkane (HFA) 134a)
UK: 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.
Protect from direct sunlight
Do not refrigerate or freeze.

Protect from frost and direct sunlight.
The canister contains a pressurized liquid.
Do not expose to temperatures higher than 50°C.
Do not puncture, break or burn the canister even when apparently empty.

6.5 Nature and contents of container

The suspension is contained in a pressurised canister in a cardboard carton.
Each canister is fitted into a plastic actuator incorporating an atomizing nozzle and fitted with a dustcap.
Pack size: 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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th June 2007

Date of last renewal: 8th June 2012

10 DATE OF REVISION OF THE TEXT

July 2017