Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Symbicort Turbohaler, 200 micrograms/6 micrograms/inhalation, inhalation powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide
160 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation.

Each metered dose contains: budesonide 200 micrograms/inhalation and formoterol fumarate dihydrate 6 micrograms/inhalation.

Excipient with known effect: Contains Lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder

Product imported from Slovakia

White powder

4 CLINICAL PARTICULARS

As per PA0970/028/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0970/028/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (which contains milk proteins)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the inhaler 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. Keep the container tightly closed, in order to protect from moisture.

6.5 Nature and contents of container

Symbicort Turbohaler is an inspiratory flow-driven, multidose powder inhaler.
The inhaler is white with a red turning grip.
Each inhaler contains 120 doses.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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Oxleasow Road
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Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/165/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2015

10 DATE OF REVISION OF THE TEXT

January 2017