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(s) with known effect: Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder

Product imported from France, Slovakia , Romania,the Netherlands and Belgium
White powder

4 CLINICAL PARTICULARS

As per PA1019/020/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/020/002

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 of this product shall be the date shown on the container and outer carton of the product as marketed 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. In each secondary package there is 1 inhaler containing 120 doses
Product sourced from Romania consists of 2 inhalers with 60 doses per pack.
Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/225/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2009
Last updated: November 2014

10 DATE OF REVISION OF THE TEXT

September 2022