Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Symbicort Turbohaler 400 micrograms/12 micrograms/inhalation inhalation powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 320 micrograms/inhalation and formoterol fumarate dihydrate 9 micrograms/inhalation.
Each metered dose contains: budesonide 400 micrograms/inhalation and formoterol fumarate dihydrate 12 micrograms/inhalation.

Excipient with known effect
Lactose monohydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder
Product imported from the Czech Republic
White powder

4 CLINICAL PARTICULARS

As per PA1019/020/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1019/020/003

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 is the date shown on the inhaler and outer carton 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, multi-dose powder inhaler. The inhaler is white with a red turning grip. In each secondary package there are 1 inhaler containing 60 doses.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/051/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th May 2015

10 DATE OF REVISION OF THE TEXT

March 2023