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: Lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder

Product imported from France, Poland, Romania and UK:

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 package of the product as marketed in the country of origin.

6.4 Special precautions for storage

Product imported from France
This medicinal product does not require any special storage conditions.
Product imported from Poland, Romania and United Kingdom
Do not store above 30°C.
Store in the original container.

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.

Product imported from Romania and Poland:
Each inhaler contains 60 doses. Each carton containers 2 inhalers.

Product imported from France and UK:
Each inahler contains 120 doses. Each carton contains 1 inhaler.

Not all pack sizes may be marketed.

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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/152/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd of June 2011

10 DATE OF REVISION OF THE TEXT

August 2018