

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Symbicort Turbohaler 100 micrograms/6 micrograms/inhalation inhalation powder

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 80 micrograms/inhalation and formoterol fumarate dihydrate 4.5 micrograms/inhalation.

Each metered dose contains: budesonide 100 micrograms/inhalation and formoterol fumarate dihydrate 6 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 Czech Republic and France*

White powder.

## 4 CLINICAL PARTICULARS

As per PA1019/020/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1019/020/001

## 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 turbohaler 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. The inhaler is made of different plastic materials.

Each inhaler contains 120 doses. There is one inhaler per carton.

**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**

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

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/051/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 29th of October 2010

**10 DATE OF REVISION OF THE TEXT**

November 2022