

# 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(s) with known effect: Lactosemonohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Inhalation powder

*Product imported from Italy, Romania and Greece*

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 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 60 or 120 doses.  
Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

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**

PPA0465/225/003

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

Date of first authorisation: 31<sup>st</sup> August 2012

## **10 DATE OF REVISION OF THE TEXT**

September 2022