

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Becotide Evohaler 50 micrograms, Pressurised Inhalation Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One metered dose contains 50 micrograms of beclometasone dipropionate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Pressurised Inhalation, Solution

*Product imported from Spain:*

Pressurised aluminium container closed with a metering valve containing a pressurised inhalation solution

## 4 CLINICAL PARTICULARS

As per PA1077/042/006

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/042/006

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Norflurane (Hydrofluoroalkane (HFA) 134a)

Ethanol Anhydrous

Glycerol

### 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 on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 30°C.

Store in the original container. Protect from frost and direct sunlight. Do not refrigerate or freeze.

As with most inhaled medications in pressurised canisters, the therapeutic effect of this medication may decrease when the canister is cold.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

### 6.5 Nature and contents of container

The inhaler comprises an aluminium can fitted with a metering valve, plastic actuator and dust cap.

Each canister contains 200 metered actuations.

## **6.6 Special precautions for disposal**

Any used medicinal product or waste material should be disposed of in accordance with local requirements. Patients should be carefully monitored in the proper use of their inhaler.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/041/005

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

Date of First Authorisation: 27<sup>th</sup> April 2007.

Date of Last Renewal: 27<sup>th</sup> April 2012.

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

March 2019

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