

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Becotide Evohaler 250 micrograms, Pressurised Inhalation Solution

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered actuation contains 250 micrograms beclometasone dipropionate.

Also contains ethanol.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Pressurised Inhalation Solution

*Product imported from: Italy & Spain*

Clear and colourless pressurised inhalation solution in an aluminium canister with a valve

### 4 CLINICAL PARTICULARS

As per PA1077/042/009

### 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/042/009

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Norflurane (HFA 134a)

Ethanol

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**

The canister contains a pressurised liquid. Do not pierce the canister. Do not expose to temperatures higher than 50°C. Replace the mouthpiece cover firmly and click it into position.

Do not store above 30°C.

Protect from light.

Do not refrigerate or freeze.

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

## **6.5 Nature and contents of container**

Over-labelled outer carton containing a pressurised container sealed with a metering valve.

The container is fitted into a plastic actuator incorporating an atomising mouthpiece and fitted with a dustcap.

Pack size: 200 metered doses

## **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**

Patients should be carefully monitored in the proper use of their inhaler.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/204/001

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

Date of first authorisation: 25<sup>th</sup> October 2013

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

October 2014