

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Becotide Evohaler 250 micrograms, Pressurised Inhalation Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One metered dose contains 250 micrograms of Beclometasone Dipropionate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised Inhalation, Solution

Product imported from Italy and Spain:

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

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

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.

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 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/041/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 19th October 2007

10 DATE OF REVISION OF THE TEXT

March 2019

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