

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

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

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 (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 medication 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

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/204/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th January 2014

10 DATE OF REVISION OF THE TEXT

June 2018