

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Flixotide Evohaler 250 micrograms per metered dose pressurised inhalation, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 250 micrograms of fluticasone propionate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised Inhalation, Suspension (Pressurised inhalation).

Product imported from Greece and the Netherlands:

Pressurised inhalation Suspension supplied in an aluminium can with metering valve and an actuator.

4 CLINICAL PARTICULARS

As per PA1077/044/015

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/044/015

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Norflurane (Hydrofluroalkane (HFA 134a))

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.

Do not refrigerate or freeze.

Store in the original package.

Protect from frost and direct sunlight.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce, burn or break the canister, even when apparently empty.

Replace the mouthpiece cover firmly and snap it into position.

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 suspension is contained in an aluminium can with a metering valve. The can is fitted into a plastic actuator incorporating an atomizing orifice and fitted with a dustcap. Pack sizes 120 metered doses per inhaler.

6.6 Special precautions for disposal and other handling

Patients should be carefully instructed in the correct use of the inhaler.

Shake before use.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/073/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 September 2001

Date of last renewal: 07 September 2006

10 DATE OF REVISION OF THE TEXT

April 2021