

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Flixotide Evohaler 125 micrograms per metered dose pressurised inhalation suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 125 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, Norway and the Netherlands:*

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

## 4 CLINICAL PARTICULARS

As per PA1077/044/014

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/044/014

## 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 pressurised can with a metering valve. The can is fitted into a plastic actuator incorporating an atomising orifice and fitted with a dustcap. Pack size: 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**

PPA0465/073/001

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

Date of first authorisation: 07 July 2001

Date of last renewal: 07 July 2006

Last updated: April 2011

Last updated: May 2014

June 2015

April 2021

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

January 2022