Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Flixotide Evohaler 50 micrograms per metered dose, Pressurised Inhalation Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 50 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:
Pressurised inhalation suspension supplied in an aluminium can with metering valve and actuator.

4 CLINICAL PARTICULARS

As per PA1077/044/013

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/044/013

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

HFA134a

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 ºC.

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 above 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 canister with a metering valve. The canisters are fitted into plastic actuators 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 inhaler.
Shake before use.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/156/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th October 2023

10 DATE OF REVISION OF THE TEXT