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.

Pressurised inhalation suspension supplied in an aluminium can with metering valve and an orange (120 dose) 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 (HFA 134a)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the device 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.

Avoid storage in direct sunlight or heat.

Do not expose to temperatures higher than 50°C. Do not pierce, break or burn 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 alloy can sealed with a metering valve. The canisters are fitted into plastic actuators incorporating an atomising orifice and fitted with dustcaps. Flixotide Evohaler is available in pack sizes of 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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/144/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th February 2015

10 DATE OF REVISION OF THE TEXT

December 2016