

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 125micrograms of fluticasone propionate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension

Product imported from Greece:

Pressurised metered dose inhaler with an orange body and a brown removable dust cap.

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 is the date shown on the canister and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C

Do not refrigerate or freeze

The canister contains a pressurised liquid

Do not expose to temperatures higher than 50°C

Do not pierce the container even when apparently empty

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 125 micrograms per metered dose, pressurised inhalation suspension is available in an over labeled pack size of 120 metered doses

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B & S Healthcare
Unit 4 Bradfield Road
Middlesex HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/124/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th January 2010

10 DATE OF REVISION OF THE TEXT

January 2015