

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Flutiform 125 microgram/5 microgram per metered dose pressurised inhalation, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose (ex-valve) contains:

- 125 micrograms of fluticasone propionate and 5 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex-actuator) of approximately 115 micrograms of fluticasone propionate and 4.5 micrograms of formoterol fumarate dihydrate.

Excipient with known effect

Each actuation contains 1 mg ethanol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

Product imported from Czech Republic

The canister contains white to off white liquid suspension. The canister is in a white actuator with a grey integrated dose indicator and a light grey mouthpiece cover.

4 CLINICAL PARTICULARS

As per PA1688/013/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1688/013/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Cromoglicate
Ethanol Anhydrous
Apaflurane HFA 227

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.

In use shelf – life: 3 months after opening the foil pouch.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. If the inhaler is exposed to freezing conditions then the patient must be advised to allow the inhaler to warm at room temperature for 30 minutes then re-prime the inhaler (see section 4.2).

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

6.5 Nature and contents of container

120 actuations per inhaler.

The actuator is white with a grey integrated dose indicator and a light grey mouthpiece cover. The suspension is contained in an aluminium pressurised canister crimped with a standard metering valve. This canister is inserted into a press-and-breathe actuator fitted with a mouthpiece cover (both made of polypropylene) and an integrated dose indicator which indicates the number of actuations (puffs) remaining. Each container delivers 120 actuations. The assembled MDI inhaler is pouched in an aluminium foil laminate and is packed in a cardboard carton.

Pack sizes:

1 inhaler (120 actuations)

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/138/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 2021

10 DATE OF REVISION OF THE TEXT

December 2021