Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Flutiform 250 microgram/10 microgram per metered dose pressurised inhalation, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose (ex-valve) contains 250 micrograms of fluticasone propionate and 10 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex-actuator) of approximately 230 micrograms of fluticasone propionate and 9.0 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 PA1688/013/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1688/013/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

disodium cromoglycate
ethanol
apaflurane HFA 227 (propellant gas)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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 PA1688/013/003).

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.

1 inhaler (120 actuations)

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

For detailed instructions on the use of the medicinal product see section 4.2 PA1688/013/003.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/508/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th September 2024

10 DATE OF REVISION OF THE TEXT