# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

AirFluSal® Forspiro® 50 microgram/250 microgram/dose, inhalation powder, predispensed

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose of AirFluSal® Forspiro® provides:
For 50 microgram/250 microgram/dose, inhalation powder, predispensed:
50 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms of fluticasone propionate
Corresponding with a delivered dose of:
45 micrograms of Salmeterol (as salmeterol xinafoate) and 233 micrograms of fluticasone propionate

Excipient with known effect: lactose monohydrate
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed.

*Product imported from Czech Republic*

White, homogenous powder.
The pre-dispensed powder, contained in blister, is delivered by a purple plastic dry-powder inhalation device.

## 4 CLINICAL PARTICULARS

As per PA0711/237/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0711/237/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the inner and outer package of the product on the market in the country of origin.

### 6.4 Special precautions for storage

Do not store above 25 °C.

### 6.5 Nature and contents of container

The plastic materials of the inhaler are:

acrylonitrile butadiene styrene, methyl methacrylate acrylonitrile butadiene styrene, polyoxymethylene and polybutylene terapthalate.

Plastic inhalation device containing an OPA/Al/PVC-Al blister with 60 pre-metered doses of powder blend.

Pack sizes:

1 device containing 60 doses

**6.6 Special precautions for disposal and other handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/004/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19th May 2017

**10 DATE OF REVISION OF THE TEXT**

September 2022