Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

AirFluSal Forspiro 50 microgram/500 microgram/dose, inhalation powder, predispensed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose of AirFluSal Forspiro provides:
For 50 microgram/500 microgram/dose, inhalation powder, predispensed:
50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms of fluticasone propionate
Corresponding with a delivered dose of:
45 micrograms of salmeterol (as salmeterol xinafoate) and 465 micrograms of fluticasone propionate

Excipient(s) 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 Poland
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 PA0711/237/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0711/237/002

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 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 25 °C.

6.5 Nature and contents of container

Plastic inhalation device containing a blister with 60 pre-dispensed doses of powder blend.
Pack size:
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

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/124/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st February 2019

10 DATE OF REVISION OF THE TEXT