Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Spiriva Respimat 2.5 microgram, inhalation solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The delivered dose is 2.5 microgram tiotropium per puff (2 puffs comprise one medicinal dose) and is equivalent to 3.124 microgram tiotropium bromide monohydrate.

The delivered dose is the dose which is available for the patient after passing the mouthpiece.

Excipient with known effect: This medicine contains 0.0011 mg benzalkonium chloride in each actuation.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation solution

Product imported from France
Clear, colourless, inhalation solution

4 CLINICAL PARTICULARS

As per PA0775/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0775/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Purified water
Hydrochloric acid 3.6 % (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the containers and outer package of the product as marketed in the country of origin.

In-use shelf-life cartridge: 3 months.
In-use shelf-life inhaler: 1 year
Recommended use: 6 cartridges per inhaler

Note: The functioning of the RESPIMAT re-usable inhaler has been demonstrated in tests for 540 actuations (corresponding to 9 cartridges).

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and contents of container

Outer carton containing re-usable Respimat inhaler and cartridge.
1 re-useable Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses).

6.6 Special precautions for disposal and other handling

Any unused 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

PPA1463/142/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2011

10 DATE OF REVISION OF THE TEXT

December 2021