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: benzalkonium chloride.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation solution

Product imported from Italy and 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
Water, purified
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 container and outer package of the product on the market 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

Type and material of the container in contact with the medicinal product:
Solution filled into a polyethylene/polypropylene cartridge with a polypropylene cap with integrated silicone sealing ring. The cartridge is enclosed within an aluminium cylinder.

Pack size and device supplied:
Single pack: 1 Respimat re-usable inhaler and 1 cartridge, providing 60 puffs (30 medicinal 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/286/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th July 2012
Date of last authorisation: 6th February 2020

10 DATE OF REVISION OF THE TEXT

November 2021