Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Spiriva 18 microgram inhalation powder, hard capsule

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 22.5 microgram tiotropium bromide monohydrate equivalent to 18 microgram tiotropium.
The delivered dose (the dose that leaves the mouthpiece of the HandiHaler device) is 10 microgram tiotropium.
Excipient with known effect: Lactose monohydrate
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder, hard capsule.

Product imported from Germany, Spain, Italy, theUnited Kingdom,France, Greece, Romania, Lithuania, Norway and Poland:
Light green hard capsules with the product code 'TI 01' and company logo printed on the capsule.

4 CLINICAL PARTICULARS

As per PA0775/002/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA0775/002/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate (which may contain small amounts of milk proteins).

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.
After first opening of the blister: 9 days
Discard the Handihaler device 12 months after first use.

6.4 Special precautions for storage

Do not store above 25°C
Do not freeze

6.5 Nature and contents of container

Blister strips containing 10 capsules
The HandiHaler is a single dose inhalation device.
Package sizes and devices supplied:

• Cardboard box containing 30 capsules (3 blister strips)

• Cardboard box containing 60 capsules (6 blister strips)
• Cardboard box containing HandiHaler device and 30 capsules (3 blister strips)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

PPA0465/186/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 24th August 2007

10 DATE OF REVISION OF THE TEXT

June 2020