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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder, hard capsule

Product imported from Bulgaria, France, Italy, Romania, Spain and the UK:
Light green hard capsules containing the inhalation powder 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 blister strips and outer carton of the product as marketed in the country of origin.
After first opening of the blister use within the next 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

Cardboard box containing HandiHaler device and 3 blister strips (3 x 10 capsules)
Cardboard box containing 3 blister strips (3 x 10 capsules)
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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/142/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 27th November 2006

10 DATE OF REVISION OF THE TEXT

October 2020