

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: Lactose monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder, hard capsule.

Product imported from Italy, the UK, Romania, Bulgaria 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 contains milk protein)

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

Aluminium / PVC / Aluminium blister strips containing 10 capsules. The HandiHaler is a single dose inhalation device made from plastic materials (ABS) and stainless steel.

Package sizes and devices supplied:

Cardboard box containing HandiHaler device and 30 capsules (3 blister strips) or cardboard box containing 30 capsules (3 blister strips).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/044/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th February 2011

10 DATE OF REVISION OF THE TEXT

May 2015