

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Spiriva Respimat 2.5 microgram, solution for inhalation

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.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Inhalation.

Product imported from Italy:
Clear, colourless, solution for inhalation.

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: 3 months

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 sizes and devices supplied:

Single pack: 1 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

B & S Healthcare
Unit 4, Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/154/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th September 2011

10 DATE OF REVISION OF THE TEXT

March 2016