Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vesitirim 5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg solifenacin succinate, corresponding to 3.8 mg solifenacin.

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Spain, Greece, France and Poland:

Each 5 mg tablet is a round, light-yellow tablet marked with the  logo and "150" on the same side.

4 CLINICAL PARTICULARS

As per PA1241/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core tablet:
Maize starch
Lactose monohydrate
Hypromellose
Magnesium stearate

Film Coating:
Macrogol 8000
Talc
Hypromellose
Titanium dioxide (E171)
Iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the blister strips and outer carton of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Container:
The tablets are packed in PVC/Aluminium blisters

Pack size in blister: 30

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/262/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd May 2011

10 DATE OF REVISION OF THE TEXT

September 2022