

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Vesitirim 10 mg Film-Coated Tablet

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg solifenacin succinate, corresponding to 7.5 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 the UK, Portugal, Greece, Poland and France:*

Each 10 mg tablet is a round, light-pink tablet marked with the  logo and '151' on the same side.

### 4 CLINICAL PARTICULARS

As per PA 1241/009/002

### 5 PHARMACOLOGICAL PROPERTIES

As per PA 1241/009/002

### 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  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/262/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 3<sup>rd</sup> May 2011

## **10 DATE OF REVISION OF THE TEXT**

February 2018