# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Vesitirim 5 mg, film-coated tablet

## 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 tablets.

*Product imported from FRANCE*

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

Maize starch
Lactose
Hypromellose (E464)
Magnesium stearate
Macrogol
Talc
Titanium dioxide (E171)
Iron oxide yellow (E172)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister and outer carton of the product as marketed 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

The tablets are packed in PVC/Aluminium blisters of 30 tablets

## 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

LTT Pharma Ltd.
Unit 18 Oxleasow Road
East Moons Moat
Redditch
Worcestershire, B98 0RE
United Kingdom

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/086/001

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

Date of first authorisation: 31st August 2012

## 10 DATE OF REVISION OF THE TEXT

April 2018