Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vesitirim 10 mg, film-coated tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Vesitirim 10 mg film-coated tablet:
Each tablet contains 10 mg solifenacin succinate, corresponding to 7.5 mg solifenacin.
Excipient(s) with known effect: lactose monohydrate (102.5 mg)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.
Vesitirim 10 mg film-coated tablet:

Product imported from GERMANY

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 PA1241/009/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1241/009/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the Blister and outer package of the re-boxed product.

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 Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/086/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

10 DATE OF REVISION OF THE TEXT