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.

Excipients: contains lactose

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from 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 PA 1241/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1241/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose
Hypromellose (E464)
Magnesium stearate
Macrogol
Talc
Titanium dioxide (E171)
Yellow iron oxide (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 strips 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

Cardboard outer containing blister strips.
Pack size: 30, 50 & 90 film-coated tablets.

Not all pack sizes may be marketed.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/130/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2010

10 DATE OF REVISION OF THE TEXT

April 2022