Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pravastatin Sodium 20 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg pravastatin sodium.
Excipient: Lactose monohydrate. For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported form the UK:
Pravastatin Tablets 20 mg: Yellow coloured, rounded rectangular shaped, biconvex, uncoated tablets debossed 'PDT' on one side and '20' on the other side

4 CLINICAL PARTICULARS

As per PA1390/002/002

5 PHARMACOLOGICAL PROPERTIES

As per PA1390/002/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose monohydrate
croscarmellose sodium
magnesium stearate
light magnesium oxide
microcelac
povidone
yellow ferric 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 container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Keep out of the reach and sight of children.

Store below 25 °C. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister packs of 28 tablets contained in an over labelled outer cardboard carton.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

WPR Healthcare Limited
Unit 10,
Ashbourne Business Park,
Rath,
Ashbourne,
Co. Meath,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0565/052/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th November 2014

10 DATE OF REVISION OF THE TEXT