Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Terazosin 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg terazosin (as terazosin monohydrochloride dihydrate).

Excipient with known effect: Each tablet contains lactose (as lactose monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from The United Kingdom.

Light pink coloured, round, flat tablets with bevelled edges and score line on one side of the tablet.
The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1390/012/003

5 PHARMACOLOGICAL PROPERTIES

As per PA1390/012/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Talc
Magnesium stearate (E470B)
Iron oxide red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product is the date shown on the blister and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store in the original packaging in order to protect from light.

6.5 Nature and contents of container

Blister of PVC/PVdC and Aluminium
Packs of 28 tablets.

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

LTT Pharma Limited
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Oxleasow Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/195/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2016

10 DATE OF REVISION OF THE TEXT