Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1 NAME OF THE MEDICINAL PRODUCT

Vastarel 20mg Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg trimetazidine dihydrochloride.
Excipients with known effect: Ponceau 4R (E124) and sunset yellow (E110)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Greece
Round, red film-coated tablets.

4 CLINICAL PARTICULARS

As per PA0068/010/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0068/010/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Maize Starch
Mannitol
Povidone
Magnesium stearate
Talc

Film coating:
Glycerol
Hypromellose
Macrogol 6000
Magnesium stearate
Ponceau 4R aluminium lake (E124)
Sunset yellow FCF aluminium lake (E110)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is 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

Do not store above 30° C.

6.5 Nature and contents of container

Blister packs of 60 tablets in a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/122/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4 February 2005
Date of renewal: 4 February 2010
Date of last renewal: April 2011
Last updated: September 2012

10 DATE OF REVISION OF THE TEXT

April 2016