Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Accupro 10 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains: quinapril hydrochloride 10.832 mg (equivalent to 10 mg quinapril base).

Excipient(s) with known effect: contains lactose monohydrate

For the full list of excipients,see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the Netherlands and the UK:
Brown, triangular film-coated tablets with a score line and '10' on one side and a score line only on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Product imported from Germany and Romania:
White triangular film-coated tablets with a score line and '10' on one side and a score line only on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA 0822/007/002.

5 PHARMACOLOGICAL PROPERTIES

As per PA 0822/007/002.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium carbonate
Lactose
Gelatin
Crospovidone

Magnesium stearate
Candelilla wax
Hypromellose
Hyprolose
Titanium dioxide (E171)
Macrogol 400
Product imported from the UK and the Netherlands also contains red 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 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 25°C.
Store in the original package.

6.5 Nature and contents of container

Blister packs of 28 (UK) and 30 (Netherlands, Romania & Germany) tablets contained in an outer cardboard carton. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/135/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 November 2004

Date of next renewal: 12 November 2009

10 DATE OF REVISION OF THE TEXT

December 2018