

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Accupro 10mg Film-coated Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Quinapril hydrochloride 10.832 mg (equivalent to 10 mg quinapril base)

Excipients:

Each tablet contains Lactose Monohydrate

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Germany.

White triangular film-coated tablets, scored on both sides and “10” embossed on one side.

4 CLINICAL PARTICULARS

As per PA0822/007/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/007/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium carbonate

Lactose monohydrate

Gelatin

Crospovidone

Magnesium stearate

Candelilla wax

Hypromellose

Hydroxypropylcellulose

Titanium dioxide (E171)

Macrogol 400

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

Do not store above 25°C

6.5 Nature and contents of container

Blister strips of 10 tablets in an over-labelled outer carton. Pack size 30 tablets.

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

B&S Healthcare
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Bradfield Road
Ruislip
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HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1328/045/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th March 2011

10 DATE OF REVISION OF THE TEXT

November 2015