

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Accupro 5 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Quinapril hydrochloride 5.416 mg (equivalent to 5 mg quinapril base).

Excipient(s) with known effect: lactose monohydrate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Greece:*

Brown, elliptical film-coated tablets with a score line and '5' on both sides. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

*Product imported from Romania:*

White, elliptical film-coated tablets with a score line and '5' on both sides. 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 0822/007/001.

## 5 PHARMACOLOGICAL PROPERTIES

As per PA 0822/007/001.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Heavy magnesium carbonate

Lactose monohydrate

Gelatin

Crospovidone

Magnesium stearate

Candelilla  
Hypromellose  
Hyprolose  
Titanium dioxide (E 171)  
Macrogol 400

Product imported from Greece also contains Iron oxide red (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 (Greece) and 30 tablets (Romania) 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**

PPA0465/135/001

**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