

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

ARICEPT 5 mg film coated tablets.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg donepezil hydrochloride.

Excipient with known effect: lactose monohydrate

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from France, Greece, Spain and the UK:*

White, round, biconvex tablets with ‘ARICEPT’ on one side and ‘5’ on the other side.

*Product imported from Italy:*

White, round, biconvex tablets with ‘ARICEPT’ on one side and ‘5’ on the other side OR white, round, biconvex tablets with no markings.

## 4 CLINICAL PARTICULARS

As per PA0822/002/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/002/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Lactose monohydrate  
Maize starch  
Microcrystalline cellulose  
Hyprolose (hydroxypropyl cellulose)  
Magnesium Stearate

#### Film coating

Talc  
Macrogol  
Hypromellose  
Titanium dioxide (E171)

### 6.2 Incompatibilities

Not applicable

### **6.3 Shelf life**

The shelf life expiry date for this product shall be 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**

Do not store above 30°C.

### **6.5 Nature and contents of container**

Blister pack containing 28 tablets in an over-labelled outer carton.

### **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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/108/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 25 February 1997

Date of last renewal: 14 February 2007

## **10 DATE OF REVISION OF THE TEXT**

September 2014