

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Aldactone 25 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25 mg of spironolactone.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

*Product imported from Spain*

Round white coloured, biconvex tablets embossed 'SEARLE 39' on one side and scored on the other. The score line is not intended for breaking the tablet

## 4 CLINICAL PARTICULARS

As per PA0822/110/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0822/110/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium sulfate dihydrate  
Corn starch gluten-free  
Povidone  
Magnesium stearate  
Peppermint Flavour

### Coating

Hydroxypropylmethylcellulose  
Polyethylene glycol  
Opaspray M-1-7111 B (white)

### 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 30°C. Keep the blisters in the outer carton in order to protect from light.

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

PVC/foil blister pack of 50 tablets contained in an overlabelled outer carton or 100 tablets in an outer carton.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal and other handling**

No special requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/418/001

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

Date of first authorisation: 17<sup>th</sup> June 2016

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

December 2020