

# 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  
polyvidone K-30  
Peppermint Flavouring  
Magnesium stearate

Coating contains:

Hydroxypropylmethylcellulose 2910  
Polyethylene glycol 400

Opadry (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 100 tablets contained in an outer carton.

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

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/223/001

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

Date of First Authorisation: 3rd May 2024

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