

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aldactone 25mg 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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/418/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th June 2016

10 DATE OF REVISION OF THE TEXT

April 2017