

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aldactone 25mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25mg of spironolactone

For a full list of excipients see 6.1.

3 PHARMACEUTICAL FORM

Film- coated tablet (Tablets)

Product imported from Spain:

Round white coloured, biconvex tablets, embossed 'SEARLE over 39' on one side and the other side half scored

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 sulphate dihydrate

Corn Starch

Povidone

Peppermint Flavour

Magnesium stearate

Coating:

Hydroxy propyl methy cellulose

Polyethylene glycol

Opaspray White M-1-7111 B

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin

6.4 Special precautions for storage

Do not store above 30°C. Keep the blisters in the outer carton.

6.5 Nature and contents of container

PVC/foil blister packs of 20 and 50 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th September 2013

10 DATE OF REVISION OF THE TEXT

December 2016