

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 a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated Tablet

Product imported from Spain:

White, round, biconvex tablets, marked with 'SEARLE 39' on one side and scored on the other.

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:

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 blister strips and outer carton of the product as marked 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

Outer carton containing blister strips
Pack size: 100 tablets (4 x 25 tablets)

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

Imbat Limited
Unit L2,
North Ring Business Park,
Santry,
Dublin 9,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/197/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st August 2014

10 DATE OF REVISION OF THE TEXT

June 2015