

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' 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 gluten free

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 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 packs of 100 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

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/133/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th October 2014

10 DATE OF REVISION OF THE TEXT