

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 Tablets

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 PA0822/110/1

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/110/1

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium sulfate dihydrate
Corn starch gluten-free
Povidone
Magnesium stearate
Peppermint Flavour

Hydroxypropylmethylcellulose
Polyethylene glycol
Opaspray M-1-7111 B (white)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for 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 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

Lexon Pharmaceuticals (Ireland) Limited
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Harcourt Centre,
Harcourt Road,
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 2022

10 DATE OF REVISION OF THE TEXT