

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aldactone 100 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 100 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, biconvex tablets embossed 'SEARLE' on one side and scored on the other.

The score line is not intended for breaking the tablet.

4 CLINICAL PARTICULARS

As per PA0822/110/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/110/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium sulfate dihydrate

Cornstarch 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. Store in the original package 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 and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/418/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th January 2022

10 DATE OF REVISION OF THE TEXT

January 2024