

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dalacin C 150 mg Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains clindamycin hydrochloride equivalent to 150 mg of clindamycin base.

Excipient(s) with known effect:

Lactose monohydrate

Medicinal product contains soya oil.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard capsule

Product imported from Hungary, Poland, Czech Republic and Spain:

Hard gelatin capsules with an opaque white body and an opaque white cap, containing a white to off-white powder. The capsule is imprinted with 'CLIN 150' and 'Pfizer'.

4 CLINICAL PARTICULARS

As per PA0822/120/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/120/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Hungary

Lactose Monohydrate

Maize starch

Talc

Magnesium stearate

Capsules:

Gelatin

Black iron oxide (E172)

Titanium dioxide (E171)

Product imported from Poland and the Czech Republic

Lactose Monohydrate

Maize starch

Talc

Magnesium stearate

Capsules:

Gelatin

Titanium dioxide (E171)

Product imported from Spain

Lactose monohydrate

Maize starch

Talc

Magnesium stearate

Capsules:

Gelatin

Erythrosine (E127)

Indigo carmine (E132)

Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Store below 25 °C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Dalacin C 150 mg Hard Capsules are available in blister packs of 16 or 24 capsules
Not all pack sizes may be marketed.

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

PPA0465/205/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th October 2007

10 DATE OF REVISION OF THE TEXT

April 2025