

# 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 Poland and Spain:*

Hard gelatin capsules with an opaque white body and an opaque white cap containing a white to off-white powder. Capsules are 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 Poland:*

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)

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## **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**

Do not store above 25°C.  
Store in the original package.

## **6.5 Nature and contents of container**

Cardboard outer carton containing blister strips.  
Pack size: 24 capsules

## **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

IMED Healthcare Ltd.  
Unit 625 Kilshane Avenue  
Northwest Business Park  
Ballycoolin  
Dublin 15  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/150/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 29<sup>th</sup> August 2014

## **10 DATE OF REVISION OF THE TEXT**

April 2025