

# 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 450mg

For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsules (hard)

*Product imported from Spain:*

Size 1, hard gelatin capsules with an opaque white body and an opaque white cap, containing a 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

#### **Capsule content:**

Lactose monohydrate

Maize starch

Talc

Magnesium stearate

#### **Composition of the capsule:**

Gelatin

Erythrosine (E127)

Carmine indigo

Indigotin (E132)

Titanium dioxide (E171)

### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf life expiry date of this product is the date shown on the blister strips and outer carton of the product as marketed in the country of origin.

### **6.4 Special precautions for storage**

Do not store above 25°C.

Store in the original packaging

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

Dalacin C 150mg Hard Capsules are available in an overlabelled outer carton containing blister packs of 24 capsules.

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

None required.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

Merit Pharmaceuticals Limited  
Unit C4/C3  
Metropoint Business Park  
Kettles Lane  
Swords  
Co Dublin  
K67 RH92  
Ireland

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23080/008/001

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

Date of first authorisation: 28th June 2013

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

January 2023