

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Duac Once Daily 10 mg/g + 50 mg/g Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of gel contains:

10 mg clindamycin as clindamycin phosphate

50 mg anhydrous benzoyl peroxide as hydrous benzoyl peroxide

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Gel.

*Product imported from Greece:*

White to slightly yellow homogeneous gel

## 4 CLINICAL PARTICULARS

As per PA1077/120/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/120/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer

Dimeticone

Disodium lauryl sulfosuccinate

Disodium edetate

Glycerol

Silica, colloidal hydrated

Poloxamer 182

Purified water

Sodium hydroxide

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

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

Shelf life of medicinal product after dispensing 2 months.

### 6.4 Special precautions for storage

Store in a refrigerator (2° C - 8° C). Do not freeze.

Storage conditions after dispensing

Do not store above 25° C.

**6.5 Nature and contents of container**

Tube in an outer carton.

Pack size: 30 g

**6.6 Special precautions for disposal**

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**

PPA0465/457/001

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

Date of first authorisation: 13<sup>th</sup> November 2020

**10 DATE OF REVISION OF THE TEXT**