

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Epiduo 0.1%/2.5% gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of gel contains:

Adapalene 1 mg (0.1% w/w)

Benzoyl Peroxide, hydrous, equivalent to 25 mg (2.5% w/w) anhydrous benzoyl peroxide.

Excipients with known effect: Propylene glycol (E1520) 40 mg/g (4.0%). Polysorbate 80

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Gel.

*Product imported from Lithuania:*

A white to very pale yellow opaque gel.

## 4 CLINICAL PARTICULARS

As per PA22743/007/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA22743/007/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Disodium edetate

Docusate sodium

Glycerol

Poloxamer

Propylene glycol (E1520)

Simulgel 600PHA (copolymer of acrylamide and sodium acryloyldimethyltaurate, isohexadecane, polysorbate 80, sorbitan oleate)

Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

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

Epiduo in-use stability is at least 6 months after first opening.

### 6.4 Special precautions for storage

Do not store above 25°C.

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

2 x 30 g white multidose container with airless pump and snap on cap

### **6.6 Special precautions for disposal**

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/519/001

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

Date of first authorisation: 7<sup>th</sup> November 2025

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