

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Solaraze 3% gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 30 mg diclofenac sodium (3% w/w).

Excipient(s) with known effect: benzyl alcohol

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gel

*Product imported from Austria*

A clear, transparent, colourless or pale yellow gel.

## 4 CLINICAL PARTICULARS

As per PA0968/004/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0968/004/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium hyaluronate  
benzyl alcohol  
macrogol monomethyl ether 350  
purified water

### 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 after opening: 6 months.

### 6.4 Special precautions for storage

Do not store above 25 °C.

### 6.5 Nature and contents of container

The product is supplied in an epoxy-phenolic lined sealed aluminium tube with a white polypropylene screw on cap with a pierced tip, in 50 g (2 x 25 g) size.

## **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**

PPA0465/488/001

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

Date of first authorisation: 17<sup>th</sup> December 2021

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

December 2021