

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Voltarol Emulgel 1% w/w Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains: Voltarol Emulgel contains diclofenac diethylammonium 1.16% w/w corresponding to diclofenac sodium 1% w/w.

Excipients with known effect: propylene glycol and benzyl benzoate

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gel

*Product imported from Germany*

Voltarol Emulgel is a white to slightly milky gel

## 4 CLINICAL PARTICULARS

As per PA0678/140/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0678/140/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

diethylamine,  
Carbomer 974 P,  
cetomacrogol,  
cocoyl caprylocaprinate,  
isopropyl alcohol,  
liquid paraffin,  
propylene glycol,  
purified water,  
perfume crème (containing benzyl benzoate)

### 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.

After first opening: 16 weeks.

### 6.4 Special precautions for storage

Do not store above 30 °C.

Keep the tube in the outer carton in order to protect from light.

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

Sealed tubes closed with a screw cap incorporating a built-in point to pierce the seal before first use.  
Available in packs of 50 g and 100 g.  
Not all pack sizes may be marketed.

### **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**

PPA0465/442/001

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

Date of first authorisation: 22<sup>nd</sup> March 2019

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

March 2022