

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 caprylocaprate,
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 25° 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: 22nd March 2019

10 DATE OF REVISION OF THE TEXT

March 2025