

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Voltarol Emulgel Extra Strength 2% w/w gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains diclofenac diethylammonium 2.32% w/w corresponding to diclofenac sodium 2 % w/w (20mg/g).

Excipient(s) of known affect:

Propylene glycol (50 mg/g gel) Butylhydroxytoluene (0.2 mg/g gel).

Perfume eucalyptus sting (containing limonene and linalool)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Product imported from Romania:

White, pleasantly perfumed, homogeneous, non-greasy gel.

4 CLINICAL PARTICULARS

As per PA0678/140/003

5 PHARMACOLOGICAL PROPERTIES

As per PA0678/140/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene

Carbomers

Cocoyl caprylocaprate

Diethylamine Isopropyl alcohol Liquid paraffin

Macrogol cetostearyl ether

Oleyl alcohol

Propylene glycol

Perfume eucalyptus sting (containing limonene and linalool) 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.

6.4 Special precautions for storage

Do not store above 30° C. Keep the tube in the outer carton.

6.5 Nature and contents of container

For the screw cap:

Aluminium laminated tube [low density polyethylene / aluminium / high density polyethylene (internal layer) or LDPE/aluminium/LLDPE, HDPE and Antiblock Masterbatch blend (internal layer)] fitted with a high density polyethylene shoulder and closed by a moulded seal. The tube is closed with a polypropylene screw cap, in blue or white, incorporating a moulded feature used to insert, twist and remove the seal before first use.

Pack size: 50g

For the flip-top cap:

Aluminium laminated tube [low density polyethylene / aluminium / high density polyethylene (internal layer) or LDPE/aluminium/LLDPE, HDPE and Antiblock Masterbatch blend (internal layer)] fitted with a high-density polyethylene shoulder. The tube is closed with a snapped-on flip-top cap made of polypropylene and thermoplastic elastomer lid. The flip-top cap has polypropylene tamper evident tabs located on each side of the cap.

Pack size: 100g

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/221/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th January 2024

10 DATE OF REVISION OF THE TEXT