**IRISH MEDICINES BOARD ACT 1995, as amended**

**Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended**

**PPA1151/069/001**
Case No: 2078468

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Imbat Limited**

**Unit L2**, **North Ring Business Park**, **Santry**, **Dublin 9**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Voltarol 1% w/w Emulgel**

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **30/07/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Voltarol 1%w/w Emulgel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 11.6mg of diclofenac diethylammonium corresponding to 10mg of diclofenac sodium (1% w/w)
Excipients: Propylene Glycol
For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Gel
*Product imported from France and Germany:*
Voltarol Emulgel is a white, pleasantly perfumed, homogenous, non-greasy emulsion in an aqueous gel.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the local symptomatic relief of pain and inflammation in:

Trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises.

Localised forms of soft tissue rheumatism

It is recommended that treatment should be reviewed after 14 days in these indications. These indications should not warrant treatment for more than 6 weeks.

For the symptomatic treatment of osteoarthritis of superficial joints such as the knee.

In the symptomatic treatment of osteoarthritis, therapy should be reviewed after 4 weeks.

### 4.2 Posology and method of administration

Topical application

*Adults**: Voltarol Emulgel should be rubbed gently into the skin. Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3-4 times daily. After application, the hands should be washed unless they are the site being treated.

Elderly: The usual adult dose may be used.

Children: Not recommended.

*It is recommended that treatment be reviewed after 14 days. These indications should not warrant treatment for more than 6 weeks.

## 4.3 Contraindications

Use in asthmatic patients hypersensitive to aspirin or other non-steroidal agents, including diclofenac. Use in patients hypersensitive to propylene glycol or isopropanol.

Previous sensitivity to diclofenac or any of the excipients

Patients with a history of hypersensitivity reactions (e.g. bronchospasm, rhinitis, urticaria) in response to Voltarol, aspirin or other non-steroidal anti-inflammatory drugs.

## 4.4 Special warnings and precautions for use

Voltarol Emulgel should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be used with occlusion. It should not be allowed to come into contact with the eyes or mucous membranes, and should
never be taken by mouth.

Side effects include itching, reddening or smarting of the skin or skin rash. Photosensitivity reactions have been observed in isolated cases.

Asthma has been rarely reported in patients using topical NSAID preparations.

Application over extensive areas for prolonged periods or application in excess of recommended dosage may give rise to systemic effects.

These include gastrointestinal disturbances and bleeding, irritability, fluid retention, rash, hepatitis, renal dysfunction, anaphylaxis and rarely blood dyscrasias, bronchospasm and erythema multiforme.

This product should only be used with great caution in patients with a history of peptic ulcer, gastrointestinal bleeding, hepatic or renal insufficiency, or bleeding diathesis, or intestinal inflammation. Circulating levels of the active drug substance are low but the theoretical risk in these patients should be considered.

This product should not be used with occlusion.

## 4.5 Interaction with other medicinal products and other forms of interaction

To date, no drug interactions during treatment with Voltarol Emulgel have been reported but the theoretical risk of the interactions listed below occurring should be borne in mind.

The following interactions occur with oral forms of Voltarol:

Lithium and digoxin: Voltarol may increase plasma levels of concurrently administered of lithium or digoxin.

Anticoagulants: Although clinical investigations do not appear to indicate that Voltarol has an influence on the effect of anticoagulants, there are isolated reports of an increased risk of haemorrhage with the combined use of diclofenac and anticoagulant therapy. Therefore to be certain that no change in anticoagulant dosage is required, close monitoring of such patients is required. As with other non-steroidal anti-inflammatory agents, diclofenac in a high dose can reversibly inhibit platelet aggregation.

Antidiabetic agents: Clinical studies have shown that Voltarol can be given together with oral antidiabetic agents without influencing their clinical effect. However there have been isolated reports of hypoglycaemic and hyperglycaemic effects which have required adjustment to the dosage of hypoglycaemic agents.

Ciclosporin: Cases of nephrotoxicity have been reported in patients receiving concomitant ciclosporin and NSAIDs, including Voltarol. This might be mediated through combined renal anti-prostaglandin effects of both the NSAID and ciclosporin.

Methotrexate: Cases of serious toxicity have been reported when methotrexate and NSAIDs are given within 24 hours of each other. This interaction is mediated through accumulation of methotrexate resulting from impairment of renal excretion in the presence of the non-steroidal anti-inflammatory drugs.

Quinolone antimicrobials: Convulsions may occur due to an interaction between quinolones and NSAIDs. This may occur in patients with or without a previous history of epilepsy or convulsions. Therefore, caution should be exercised when considering the use of a quinolone in patients who are already receiving an NSAID.

Other NSAIDs and steroids: Co-administration of Voltarol with other systemic NSAIDs and steroids may increase the frequency of unwanted effects. Concomitant therapy with aspirin lowers the plasma levels of each, although the clinical significance is unknown.

Diuretics: Various NSAIDs are liable to inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, hence serum potassium should be monitored.

## 4.6 Pregnancy and lactation

Since no experience has been acquired with Voltarol Emulgel in pregnancy or lactation, it is not recommended for use in these circumstances.

Use of prostaglandin synthetase inhibitors may result in premature closure of the ductusarteriosus or uterine inertia, such drugs are therefore not recommended during the last trimester of pregnancy.

Following doses of 50mg gastro-resistant tablets every 8 hours, traces of active substance have been detected in breast milk, but in quantities so small that no undesirable effects on the infant are to be expected.

## 4.7 Effects on ability to drive and use machines

Patients who experience dizziness or other central nervous system disturbances, including visual disturbances, while taking NSAIDs should refrain from driving or operating machinery.

## 4.8 Undesirable effects

Voltarol Emulgel is usually well tolerated. Itching, reddening or smarting of the skin, or skin rash, may occasionally occur. Photosensitivity reactions have been observed in isolated cases.

Systemic absorption of Voltarol Emulgel is low compared with plasma levels obtained following oral forms of Voltarol. However, where Voltarol Emulgel is applied to a relatively large area of skin and over a prolonged period, the possibility of systemic side effects cannot be completely excluded.

Asthma has been rarely reported in patients using topical NSAID preparations.

## 4.9 Overdose

The low systemic absorption of topical diclofenac renders overdosage extremely unlikely. In the event of accidental ingestion, resulting in significant systemic side-effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory drugs should be used.

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from Voltarol overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

*Pharmacotherapeutic group:*
Non-steroidal anti-inflammatory drug (NSAID)

*Mode of action*:
Voltarol Emulgel is an anti-inflammatory and analgesic preparation designed for external application. Due to an aqueous-alcoholic base it exerts a soothing and cooling effect.

## 5.2 Pharmacokinetic properties

When Voltarol Emulgel is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed when determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Voltarol Emulgel.
After topical administration of Voltarol Emulgel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of Voltarol.

## 5.3 Preclinical safety data

Preclinical studies conducted with Voltarol Emulgel did not reveal any clinically relevant toxicological effects.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Diethylamine
Carbomer
Cetomacrogol
Caprylic/capric acid fatty alcohol ester
Isopropyl alcohol
Liquid paraffin
Perfume
Propylene glycol
Purified Water

## 6.2 Incompatibilities

None known.

## 6.3 Shelf Life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

## 6.4 Special precautions for storage

Do not store above 25ºC.

## 6.5 Nature and contents of container

Cardboard outer containing an aluminium tube. Pack size 50g.

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

## 7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/69/1

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

Date of First Authorisation 16th May 2008

## 10 DATE OF REVISION OF THE TEXT

May 2010