

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

VOLTAREN EMULGEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Diclofenac diethylamine 1.16%

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White emulsion in an aqueous gel.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the short term (up to 2 weeks) local symptomatic treatment of the following musculoskeletal inflammatory conditions:

- Acute soft-tissue injuries, including sprains, strains, tendinitis and sports injuries
- Localised forms of soft-tissue rheumatism e.g. tendinitis (tennis elbow) and bursitis.

For the short term (up to 3 weeks) relief of pain in non-serious arthritis (i.e. mild and localised forms of osteoarthritis) of the knee or fingers. Relief of osteoarthritis pain builds up gradually over the first few days of treatment, a significant effect can be expected after one week of application.

4.2. Dosage and Method of Administration

Adults and adolescents aged 12 years and over:

Voltaren Emulgel is applied locally to the skin 3 or 4 times daily and rubbed in gently. The amount needed depends on the size of the painful site. For example, 2 to 4 g Voltaren Emulgel (a quantity ranging in size from a cherry to a walnut) is sufficient to apply to an area of about 400-800 cm². After application, the hands should be washed, unless they are the site being treated.

The duration of treatment depends on the indication and the response obtained. The gel should not be used for more than 14 days for soft-tissue injuries or soft-tissue rheumatism, or 21 days for osteoarthritis pain, unless recommended by a doctor.

When used without medical prescription, patients should consult their doctor or pharmacist if the condition does not improve within 7 days, or if it gets worse.

Children:

Voltaren Emulgel is not recommended for use in children below 12 years of age.

Elderly:

The usual adult dose may be used.

4.3. Contraindications

- Known hypersensitivity to diclofenac, propylene glycol, isopropyl alcohol, or the other ingredients in the gel.
- Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Last trimester of pregnancy.

4.4. Special Warnings and Precautions for Use

Voltaren Emulgel should be applied only to intact, healthy skin and not to skin wounds, infections, exudative dermatoses or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should never be taken by mouth.

Discontinue the treatment if a skin rash develops after applying the product.

Voltaren Emulgel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

The likelihood of systemic side effects occurring following topical diclofenac is small compared with the frequency of side effects following oral diclofenac. However, the possibility of systemic side effects cannot be excluded, particularly when Voltaren Emulgel is applied to relatively large areas of skin or for periods longer than 3 weeks. In case such usage is envisaged, the product information on Voltaren Tablets and Suppositories should be consulted. In general, topical NSAIDs should be used with caution in those patients with a history of (or active) gastro-intestinal ulceration or bleeding, or severe renal impairment.

4.5. Interactions with Other Medicines and Other Forms of Interaction

There are isolated reports of suspected interaction of topical formulations of diclofenac with oral anticoagulants.

The concurrent use of NSAIDs and warfarin has been associated with severe, sometimes fatal, haemorrhage. The exact mechanism of the interaction between NSAIDs and warfarin is unknown, but may involve enhanced bleeding from NSAID-induced gastrointestinal ulceration or an additive effect of anticoagulation by warfarin and inhibition of platelet function by NSAIDs. Since systemic absorption of diclofenac from topical application of the gel is very low, such interactions are very unlikely. Systemic reactions are unlikely to occur when Voltaren Emulgel is used as recommended. Nevertheless, the possibility of such an interaction should be borne in mind.

4.6. Fertility, Pregnancy and Lactation

Use in Pregnancy (Category C)

The use of diclofenac in pregnant women has not been studied; therefore, Voltaren Emulgel should not be used during pregnancy. Diclofenac is contraindicated during the third trimester of pregnancy, owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus.

Animal studies have not shown any direct or indirect harmful effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Animal studies did see some degree of reproductive toxicity, although this was generally associated with maternal toxicity, with no indication of developmental toxicity.

There was no evidence that diclofenac had a teratogenic potential in mice, rats or rabbits. Diclofenac had no influence on the fertility of parent animals in rats. The prenatal, perinatal and postnatal development of the offspring was not affected.

Use in Lactation

It is not known whether topical diclofenac is excreted in breast milk; therefore, Voltaren Emulgel is not recommended during breast-feeding. If there are compelling reasons for using it, it should not be applied to the breasts or to large areas of skin, nor should it be used for a prolonged period.

4.7. Effects on ability to drive and use machines

Cutaneous application of Voltaren Emulgel is unlikely to influence on the ability to drive and use machines.

4.8. Undesirable Effects

Undesirable effects include mild and passing skin reactions at the site of application. In very rare instances, allergic reactions may occur.

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1,000$), very rare ($< 1/10,000$), including isolated reports.

Table 1

Infections and infestations Very rare:	Rash pustular
Immune system disorders Very rare:	Hypersensitivity (including urticaria), angioedema
Respiratory, thoracic and mediastinal disorders Very rare:	Asthma
Skin and subcutaneous tissue disorders Common: Rare: Very rare:	Rash, eczema, erythema, dermatitis (including contact dermatitis), pruritis Dermatitis bullous Photosensitivity reaction

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to <https://nzphvc.otago.ac.nz/reporting/>.

4.9. Overdose

The low systemic absorption of topical diclofenac renders overdosage extremely unlikely. However, undesirable effects, similar to those observed following an overdose of Voltaren tablets, can be expected if Voltaren Emulgel is inadvertently ingested (1 tube of 100 g contains the equivalent of 1 g diclofenac sodium).

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. For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

ATC code M02A A15 – topical products for joint and muscular pain. Anti-inflammatory preparations, non-steroids for topical use.

Mechanism of action

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with pronounced analgesic, anti-inflammatory and antipyretic properties. Inhibition of prostaglandin synthesis is the primary mechanism of action of diclofenac.

Voltaren 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.

In inflammation and pain of traumatic or rheumatic origin, Voltaren Emulgel has been shown to relieve pain, reduce oedema, and shorten the time to return of normal function.

5.2. Pharmacokinetic Properties

Absorption

When Voltaren Emulgel is applied locally, the active substance is absorbed through the skin. The amount of diclofenac absorbed through intact skin is proportional to the contact time and skin area covered with Voltaren Emulgel, and depends on the total topical dose and the hydration of the skin. Absorption amounts to about 6% of the dose of diclofenac after topical application of 2.5 g Voltaren Emulgel per 500 cm² skin, determined by reference to the total renal elimination compared with Voltaren tablets. Occlusion over a period of 10 hours leads to a three-fold increase in the amount of diclofenac absorbed. No information is available on the clinical effects and consequences of use under occlusion.

Distribution

After topical administration of Voltaren Emulgel to hand and knee joints, diclofenac can be measured in plasma, synovial tissue, and synovial fluid. Maximum plasma concentrations of diclofenac after topical administration of Voltaren Emulgel are about 100 times lower than after oral administration of Voltaren tablets. 99.7% of diclofenac binds to serum proteins, chiefly to albumin (99.4%).

Metabolism

Biotransformation of diclofenac involves partly glucuronidation of the intact molecule, but mainly single and multiple hydroxylation resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, however, to a much smaller extent than diclofenac. Metabolism of diclofenac following percutaneous and oral administration is similar.

Elimination

The total systemic clearance of diclofenac from plasma is 263 ± 56 mL/min (mean value \pm SD). The terminal plasma half-life is 1 to 2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1-3 hours. One metabolite, 3'-hydroxy-4'-methoxy-diclofenac, has a much longer plasma half-

life. However, this metabolite is virtually inactive. Diclofenac and its metabolites are excreted mainly in the urine.

Characteristics in patients:

No accumulation of diclofenac and its metabolites is to be expected in patients suffering from renal impairment. In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of diclofenac are the same as in patients without liver disease.

5.3. Preclinical safety data

Preclinical data from acute and repeated dose toxicity studies, as well as from genotoxicity, mutagenicity, and carcinogenicity studies with diclofenac revealed no specific hazard for humans at the intended therapeutic doses. Voltaren Emulgel was well tolerated in a variety of studies. There was no potential for phototoxicity and Voltaren Emulgel caused no skin sensitisation.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Diethylamine, carbomer 934P, cetomacrogol 1000, coco-caprylate/caprate, isopropyl alcohol, liquid paraffin, perfume, propylene glycol, water.

6.2. Incompatibilities

No known incompatibilities

6.3. Shelf life

36 months

6.4. Special Precautions for storage

Store below 30 degrees Celsius.

6.5. Nature and contents of container

Available in tubes of 20 g, 50 g, 100 g and 120 g.

6.6. Special precautions for disposal and other handling

No special requirements

7. MEDICINE SCHEDULE

General sale medicine

8. SPONSOR

GlaxoSmithKline Consumer Healthcare
Level 11, Zurich House
21 Queen Street
Auckland 1010
New Zealand
FREECALL NZ: 0800 540 144

9. DATE OF FIRST APPROVAL

23/08/1985

10. DATE OF REVISION OF THE TEXT

22 October 2018

Summary table of changes

<u>Section changes</u>	<u>Summary of new changes</u>
All	Transferred to new data sheet template
4.4 Special warnings and precautions for use	Addition of statement: Discontinue the treatment if a skin rash develops after applying the product. Addition of 'airtight' before 'occlusive dressing'.

Trademarks are owned by or licensed to the GSK group of companies.