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).

Excipients of known affect:
Propylene glycol (50 mg/g gel)
Buthylhydroxytoluene (0.2 mg/g gel).
Perfume eucalyptus sting containing limonene and linalool (1.0 mg/g)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel
White, pleasantly perfumed, homogeneous, 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.

- adults and adolescents 14 years and over.

4.2 Posology and method of administration

For cutaneous use only.

Adults and adolescents 14 years and over:
Voltarol Emulgel Extra Strength 2% w/w Gel provides lasting pain relief of up to 12 hours (applied 2 times daily - morning and evening). It should be rubbed gently into the skin at the affected area.

The amount needed depends on the size of the painful area: 2 g to 4 g (a quantity ranging in size from a cherry to a walnut) of gel is sufficient to treat an area of about 400-800 cm^2. After application, the hands should be wiped with a paper towel and then washed, unless the hands are the area to be treated.

If too much gel is accidentally applied, the excess gel should be wiped with a paper towel.
The paper towel should be disposed in the household waste to prevent unused product reaching the aquatic environment.
Before applying a bandage, the gel should be left to dry for a few minutes on the skin.

It is recommended that treatment be limited to 14 days.

If the condition does not improve or worsens within 7 days of starting treatment, patient

should consult their doctor to exclude an alternative underlying cause of pain.

In adolescents aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

Use in the elderly: The usual adult dose may be used.

Children and adolescents below 14 years:
There are insufficient data on efficacy and safety available for children and adolescents below 14 years (see also contraindications section 4.3).

4.3 Contraindications

Patients with or without chronic asthma in whom asthma, angioedema, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents.
Hypersensitivity to diclofenac, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
Hypersensitivity to any other ingredient of the gel.
During the last trimester of pregnancy.
The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warnings and precautions for use

Voltarol Emulgel Extra Strength 2% w/w Gel 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.

The possibility of experiencing systemic adverse events (those associated with the use of systemic forms of diclofenac) should be considered if topical diclofenac is used at a higher dosage or for a longer period of time than recommended (see Dosage and Administration. 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 can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

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

Like other drugs that inhibit prostaglandin synthetase activity, diclofenac and other NSAIDs can precipitate bronchospasm if administered to patients suffering from, or with a previous history of, bronchial asthma.

Voltarol Emulgel Extra Strength 2% w/w Gel contains propylene glycol, which may cause skin irritation. It also contains butylhydroxytoluene which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

Voltarol Emulgel Extra Strength 2% w/w Gel contains fragrance with limonene and linalool, which may cause allergic reactions.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from topical application is very low, interactions are unlikely.

4.6 Fertility, pregnancy and lactation

1.1 Pregnancy

There is no clinical data from the use of diclofenac during pregnancy.
The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic [product name] exposure reached after topical administration can be harmful to an embryo/fetus. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

The mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour. Consequently, diclofenac is contraindicated during the third trimester of pregnancy (see section 4.3).

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Voltarol Emulgel Extra Strength 2% w/w Gel no effects on the suckling child are anticipated. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, **Voltarol Emulgel Extra Strength 2% w/w Gel** should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time (see section 4.4).

4.7 Effects on ability to drive and use machines

Cutaneous application of topical diclofenac has no 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: *very common* (≥ 1/10); *common* (≥ 1/100 to < 1/10); *uncommon* (≥ 1/1,000 to < 1/100); *rare* (≥ 1/10,000 to < 1/1,000); *very rare* (< 1/10,000); *not known*: cannot be estimated from the available data. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Table 1

Infections and infestations:	Very rare:	Rash pustular.
Immune system disorders:-	Very rare:	Hypersensitivity (including urticaria), angioneurotic oedema
Respiratory, thoracic and mediastinal disorders	Very rare:	Asthma.
Skin and subcutaneous tissue disorders	Common:	Dermatitis (including contact dermatitis), rash, erythema, eczema, pruritus.

	Rare:	Dermatitis bullous
	Very rare:	Photosensitivity reaction

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Signs and symptoms

The low systemic absorption of topical diclofenac renders overdosage 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.

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from diclofenac 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.

Further management should be as clinically indicated or as recommended by the national poisons centres, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Mechanism of action and pharmacodynamic effects:
Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with pronounced analgesic, anti-inflammatory and antipyretic properties.
Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).

Voltarol Emulgel Extra Strength 2% w/w Gel is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and pain of traumatic or rheumatic origin, **Voltarol Emulgel Extra Strength 2% w/w Gel** has been shown to relieve pain. In one ankle sprain study (VOPO-P-307) within 3 days of starting treatment, subjects treated with **Voltarol Emulgel Extra Strength 2% w/w Gel** reported significantly decreased pain on movement scores versus placebo treated subjects, including a subgroup of patients with severe pain.

Due to an aqueous-alcoholic base the gel also exerts a cooling effect.

5.2 Pharmacokinetic properties

Absorption

The quantity of diclofenac absorbed through the skin is proportional to the size of the treated area, and depends on both the total dose applied and the degree of skin hydration. After topical application to approximately 400 cm^2 of skin, the extent of systemic exposure as determined by plasma concentration of **Voltarol Emulgel Extra Strength 2% w/w Gel** (2 applications/day) was equivalent to diclofenac 1.16% gel (4 applications/day). The relative bioavailability of diclofenac (AUC ratio) for **Voltarol Emulgel Extra Strength 2% w/w Gel** versus tablet was 4.5% on day 7 (for equivalent diclofenac sodium dose). Absorption was not modified by a moisture and vapour permeable bandage.

Distribution

Diclofenac concentrations have been measured from plasma, synovial tissue and synovial fluid after application of topical diclofenac to hand and knee joints. Maximum plasma concentrations were approximately 100 times lower than after oral administration of the same quantity of diclofenac. 99.7 % of diclofenac is bound to serum proteins, mainly albumin (99.4 %). From the skin and underlying tissue, diclofenac preferentially distributes and persists in deep inflamed tissues (such as the joint), rather than in the bloodstream. Diclofenac is found in concentrations up to 20 times higher than in plasma.

Biotransformation

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 the phenolic metabolites are biologically active, however, to a much smaller extent than diclofenac.

Elimination

The total systemic clearance of diclofenac from plasma is 263 ± 56 ml/min. The terminal plasma half-life is 1-2 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 longer half-life but 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 studies conducted with Voltarol Emulgel did not reveal any clinical relevant toxicological effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene [E 321]
Carbomers
Cocoyl caprylocaprate
Diethylamine
Isopropyl alcohol
Liquid paraffin
Macrogol cetostearyl ether
Oleyl alcohol
Propylene glycol [E 1520]
Perfume eucalyptus sting (containing limonene and linalool)
Purified water

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

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 sizes: 20g, 30g, 50g and 100g

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

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited,
Clocherane, Youghal Road,
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Co. Waterford, X35 Y983,
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8 MARKETING AUTHORISATION NUMBER

PA0678/140/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

November 2025