Information for healthcare professionals from the Swiss Compendium of Medicines®

VOLTAREN EMULGEL

GSK Consumer Healthcare Schweiz AG

Composition

Active substance: diclofenac diethylamine.

Excipients: carbomer, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, macrogol cetostearyl ether, paraffin wax, propylene glycol, fragrance (containing benzyl benzoate), purified water.

Pharmaceutical form and active substance quantity per unit

100 g of Voltaren Emulgel contains 1.16 g of the active substance diclofenac diethylamine, corresponding to 1 g of diclofenac sodium.

The formulation is an oil emulsion in an aqueous gel with added isopropanol and propylene glycol.

Indications/Possible uses

For external use in the treatment of pain, inflammation and swelling in case of:

- injuries to tendons, ligaments, muscles and joints, e.g. sprains, contusions, muscle strains and back pain following sporting activity or an accident.
- localised forms of soft tissue rheumatism, e.g. tendinitis (tennis elbow), shoulder hand syndrome, bursitis, polyarthropathies;
- and for the symptomatic treatment of osteoarthritis of the small and medium-sized superficial joints, e.g. finger or knee joints.

Posology/Use

The product is for external use only.

Adults and adolescents aged 12 years and above

Depending on the size of the painful area to be treated, gently rub into the skin 2-4 g of Voltaren Emulgel (an amount the size of a cherry or a walnut is enough to treat an area of approximately 400-800 cm^2) 3 to 4 times per day.

Treatment duration depends on the indication and the response elicited. It is recommended to review treatment after 2 weeks if the symptoms have not improved. Voltaren Emulgel should not be used for more than 14 days. Wash hands thoroughly after use (except when treating the fingers).

Children less than 12 years of age

The use and safety of Voltaren Emulgel in children less than 12 years of age have not yet been studied systematically and its use is therefore not recommended in this age group.

Patients over 65 years of age

The normal daily dose for adults can be used.

Contraindications

Known hypersensitivity to diclofenac (active substance) or to any of the excipients (e.g. isopropanol or propylene glycol); see full list under "Composition").

In patients who have an asthma attack, angioedema, urticaria or acute rhinitis as a reaction to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs, such as ibuprofen.

During the third trimester of pregnancy (see the note in the section "Pregnancy/Lactation").

Warnings and precautions

Apply Voltaren Emulgel only to undamaged and healthy skin with no lesions or open wounds.

Avoid contact between the product and the eyes and mucous membranes. Do not swallow.

Immediately stop treatment if a rash appears after use.

Voltaren Emulgel contains propylene glycol and benzyl benzoate: these excipients may cause mild, localised skin irritation in some patients.

Voltaren Emulgel should not be used with airtight, occlusive dressings.

When Voltaren Emulgel is applied to a larger area and for a longer period of time than recommended (see "Posology/Use"), the occurrence of systemic adverse effects cannot be completely ruled out. In such cases, refer to the information for healthcare professionals on oral forms of diclofenac.

Interactions

It is unlikely that interactions will occur, in view of the low systemic absorption when applied topically. See also the last paragraph of the "Warnings and Precautions" and "Undesirable effects" sections.

Pregnancy/Lactation

PREGNANCY

No controlled studies are available in pregnant women. Therefore, Voltaren Emulgel should not be used in pregnant women. Voltaren Emulgel is contraindicated during the third trimester of pregnancy, owing to the potential risk of premature closure of the ductus arteriosus, possible inhibition of uterine contractions, as well as possible foetal renal function disorders that may progress to renal failure with oligohydramnios.

In animal studies no direct or indirect adverse effects on pregnancy, embryonic/foetal development, delivery and postnatal development have been found (see "Preclinical Data").

Lactation

It is not known whether topically applied diclofenac is excreted in breast milk. Therefore, Voltaren Emulgel should not be used in breastfeeding women. Where indicated as a matter of necessity, do not apply Voltaren Emulgel to the breasts, to large areas of skin or over a prolonged period of time.

Effects on ability to drive and use machines

Not applicable.

Undesirable effects

Undesirable effects are listed by system organ class and by frequency.

Within each frequency grouping, undesirable effects are classed in order of decreasing severity.

Frequencies

"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).

Infections and infestations

Very rare: pustular skin eruption.

Immune system disorders

Very rare: angioedema, hypersensitivity reactions (including urticaria).

Respiratory, thoracic and mediastinal disorders

Very rare: asthma.

Skin and subcutaneous tissue disorders

Common: dermatitis (including contact dermatitis), skin eruption, redness, eczema, pruritus.

Rare: bullous dermatitis.

Very rare: photosensitisation.

The probability of systemic undesirable effects occurring with the topical form of diclofenac is low in comparison with the frequency of undesirable effects observed in case of treatment with oral diclofenac.

However, the occurrence of systemic adverse effects cannot be completely ruled out when Voltaren Emulgel is applied to a larger area and for a prolonged period of time. In this case, refer to the information for healthcare professionals on oral forms of Voltaren.

Overdose

An overdose is unlikely, considering the low systemic absorption of diclofenac when applied topically.

The expected adverse effects in case of accidental ingestion of Voltaren Emulgel (one 100 g tube corresponds to 1 g sodium diclofenac) are similar to those observed in case of overdose with diclofenac tablets. If significant systemic undesirable effects occur following misuse or accidental consumption (e.g. in children), the general therapeutic measures recommended for intoxication with non-steroidal anti-inflammatory drugs should be taken, as applicable, in consultation with Tox Info Suisse.

Properties/Effects

ATC Code: M02AA15

MECHANISM OF ACTION AND PHARMACODYNAMICS

Diclofenac is a non-steroidal antirheumatic (NSAR) with significant analgesic, anti-inflammatory and antipyretic properties.

Voltaren Emulgel is an anti-inflammatory and analgesic product for external use. The emulgel is a non-greasy, white cream and is easily absorbed by the skin. As a result of its water-alcohol base, it has a soothing and cooling effect.

The proven inhibition by diclofenac of prostaglandin biosynthesis is considered to be a significant component of its mechanism of action.

In case of inflammation of traumatic origin, Voltaren Emulgel relieves pain and reduces oedema.

Pharmacokinetics

ABSORPTION

The quantity of diclofenac absorbed by the skin is proportional to the time Voltaren Emulgel is in contact with the skin, and to the surface area treated; it also depends on the total dose applied and skin hydration. Approximately 6% of the diclofenac dose is absorbed after topical application of 2.5 g of Voltaren Emulgel over a skin surface area of 500 cm^2, calculated in relation to total renal elimination compared with that obtained with Voltaren tablets. Diclofenac absorption is tripled if the treated area is covered by an occlusive dressing for 10 hours.

Distribution

After topical application of Voltaren Emulgel to hand and knee joints, diclofenac levels can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac obtained after topical application of Voltaren Emulgel are approximately 100 times lower than those obtained with Voltaren tablets. 99.7% of diclofenac is bound to serum proteins, primarily to albumin (99.4%).

Metabolism

Diclofenac biotransformation is partly by glucuronidation of the whole molecule, but especially by simple or multiple hydroxylation, leading to the formation of phenolic metabolites, which are then eliminated mostly in glucuronidated form. Two of these phenolic metabolites are biologically active, but to a much lower degree than diclofenac.

Elimination

Total plasma clearance of diclofenac is 263 ± 56 mL/min (mean ± standard deviation). Terminal plasma half-life is 1-2 hours. Four of the metabolites, including the active two, also have a short plasma half-life of 1-3 hours. Another metabolite, 3'-hydroxy-4'-methoxydiclofenac, has a significantly longer half-life, but is practically inactive. Diclofenac and its metabolites are excreted mainly in the urine.

Kinetics for some patient groups

Diclofenac and its metabolites should not be expected to accumulate in case of renal failure.

The kinetics and metabolism of diclofenac are the same in patients with chronic hepatitis or compensated cirrhosis as in patients without liver disease.

Preclinical data

Preclinical data from studies with diclofenac on acute toxicity, repeated dose toxicity, genotoxicity, mutagenicity and carcinogenicity did not reveal any specific risk to humans at the recommended therapeutic doses.

No teratogenic effect was observed in mice, rats and rabbits. Diclofenac had no effect on the fertility of the parents (rats) or the pre-, peri- or post-natal development of the offspring.

Different studies did not provide any indications that Voltaren Emulgel induces phototoxicity or skin sensitisation.

Specific comments

STABILITY

The medicinal product must not be used after the date that appears on the container after "EXP".

Comments on storage

Store between 15°C and 30 °C.

Keep out of the reach of children.

Marketing authorisation number

47344 (Swissmedic).

Marketing authorisation holder

GSK Consumer Healthcare Schweiz AG, Risch.

Date of revision

April 2019.

Presentation

	Quantity	CHF	Discount cat.	Reimbursement cat.
VOLTARENE émulgel 1%	50 g tube	8.70	D	LS O
	100 g tube		D	

Published on 02 September 2019