HALEON

Voltaren

3 Back & Muscle Pain Gel

Emulgel 1%

Diclofenac diethylamine 1.16g/100g

• Relieves pain • Reduces swelling
• Combats inflammation

1. BRAND OR PRODUCT NAME

Voltaren Emulgel 1%

2. NAME AND STRENGTH OF ACTIVE SUBSTANCE(S)

One gram of Voltaren Emulgel 1% contains 11.6 mg (1.16% w/w) of diclofenac diethylamine, which corresponds to 10 mg (1% w/w) of diclofenac sodium.

3. PRODUCT DESCRIPTION

White to practically white, soft, homogeneous, cream-like gel.

4. PHARMACODYNAMICS

ATC Code
M02AA15
Mechanism of action and pharmacodynamic effects
Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with effective analgesic, anti-inflammatory and antipyretic properties. Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).
Voltaren Emulgel 1% is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and pain of traumatic or rheumatic origin, Voltaren Emulgel 1% relieves pain and decreases swelling.

5. PHARMACOKINETICS

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.
Absorption amounts to about 6% of the applied dose of diclofenac after topical application of 2.5 g Voltaren Emulgel 1% on 500 cm² skin, determined by total renal elimination, compared with Voltaren tablets. A 10-hour occlusion leads to a three-fold increase in the amount of diclofenac absorbed.

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Distribution
Diclofenac concentrations have been measured from plasma, synovial tissue and synovial fluid after topical administration of a diclofenac diethylamine gel to hand and knee joints. Maximum plasma concentrations are 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%).
Diclofenac accumulates in the skin which acts as reservoir from where there is a sustained release of drug into underlying tissues. 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 tissues at concentrations up to 20 times higher than in plasma.
Metabolism
The biotransformation of diclofenac involves single and multiple hydroxylation steps followed by glucuronidation, and glucuronidation of the intact molecule.
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.
Special populations
Renal and hepatic impairment
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.

6. PRECLINICAL SAFETY DATA

Non-clinical data from acute and repeated dose toxicity studies, as well as from genotoxicity, and carcinogenicity studies with diclofenac revealed no specific hazard for humans at the intended therapeutic doses. Topical diclofenac was well tolerated in a variety of studies. There was no potential for phototoxicity and diclofenac-containing gel caused no skin sensitisation.

Reproductive Toxicology
Diclofenac demonstrated no evidence of impairment on the fertility of male or female rats. There was no evidence that diclofenac had a teratogenic potential in mice, rats or rabbits. The prenatal, perinatal and postnatal development of the offspring was not affected.

7. INDICATION

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

- injuries of the tendons, ligaments, muscles and joints, e.g. sprains, bruises, strains and back pain after sport or accidents;
- localized forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathies;
- and for the symptomatic treatment of osteoarthritis of small and medium-sized joints located close to the skin such as the finger joints or knee joints.

8. RECOMMENDED DOSAGE

For cutaneous use only.
Patients should consult their doctor if the condition does not improve or worsens within 7 days of starting treatment.
For adults and adolescents aged 12 years and over.
This medicine should be applied over the affected area 3 or 4 times daily and rubbed gently into the skin. The amount needed depends on the size of the painful area: 2 g to 4 g Voltaren Emulgel 1% (a quantity ranging in size from a cherry to a walnut) is sufficient to treat 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 clinical response. The product should not be used for more than 14 days. Voltaren Emulgel 1% can also be used as an adjunctive therapy with other pharmaceutical forms of Voltaren.
Elderly patients (over 65 years of age)
The usual adult dosage may be used.
Children or adolescents (under 12 years of age)
The use and safety of Voltaren Emulgel 1% in children under 12 years has not been tested systematically and is not recommended.

9. ROUTE OF ADMINISTRATION

Topical.

10. CONTRAINDICATIONS

- Known hypersensitivity to diclofenac or to any of the excipients contained in the emulgel (see list of excipients).

- Patients in whom asthma, angioedema, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- During the last trimester of pregnancy.

11. WARNINGS AND PRECAUTIONS

Special warnings and precautions for use

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 Recommended Dosage). Topical diclofenac should be applied only to intact, non-diseased skin, and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should not be ingested. Discontinue the treatment if a skin rash develops after applying the product. Topical diclofenac can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Information concerning excipients

Voltaren Emulgel 1% contains propylene glycol and benzyl benzoate, which may cause mild, localised skin irritation in some people.

Effects on ability to drive and use machines

Cutaneous application of Voltaren Emulgel has no influence on the ability to drive and use machines.

12. INTERACTIONS WITH OTHER MEDICAMENTS

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

13. STATEMENT ON USAGE DURING PREGNANCY AND LACTATION

Pregnancy

There are insufficient data on the use of diclofenac in pregnant women. Diclofenac should be used during the first two trimesters of pregnancy only if the expected benefit justifies the potential risk to the foetus. As with other NSAIDs, use of diclofenac during the third trimester of pregnancy is contraindicated owing to the possibility of uterine inertia, fetal renal impairment with subsequent oligohydramnios and/or premature closure of the ductus arteriosus.

Lactation

It is not known whether topical diclofenac is excreted in breast milk. Diclofenac should only be used during lactation if the expected benefit justifies the potential risk to the newborn. If there are compelling reasons for using it, it should not be applied to the breasts nor should it be used at a higher dosage or for a longer period of time than recommended.

14. ADVERSE EFFECTS/ UNDESIRABLE EFFECTS

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: 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). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

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: Dermatitis (including contact dermatitis), rash, erythema, eczema, pruritus.
Rare: Dermatitis bullous.
Very rare: Photosensitivity reaction.

15. OVERDOSE AND TREATMENT

The low systemic absorption of topical diclofenac renders overdose very unlikely.
However undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if topical diclofenac is ingested (1 tube of 100 g contains the equivalent of 1 g diclofenac sodium).
In the event of accidental ingestion, resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory medicines should be used.
Further management should be as clinically indicated or as recommended by the national poisons centres where available.

16. LIST OF EXCIPIENTS

Carbomer
Macrogol cetostearyl ether (Cetomacrogol 1000)
Cocoyl caprylocaprate (Cetiol LC)
Diethylamine
Isopropyl alcohol
Propylene glycol
Liquid paraffin
Perfume Cream 45 (containing benzyl benzoate)
Purified water

17. STORAGE CONDITIONS

Do not store above 30 °C. Protect from heat.

18. PACKAGING

Pack sizes: 10g, 20g, 30g, 50g
Not all pack sizes may be marketed.

19. NAME AND ADDRESS OF MANUFACTURER

Haleon CH SARL
Route de l'Etraz,
1260 Nyon, Switzerland.

20. PRODUCT REGISTRATION HOLDER

Malaysia – Haleon Malaysia Sdn. Bhd. (Registration No: 195901000115 (3467-X)), Lot 89, Jalan Enggang, Ampang/ Hulu Kelang Industrial Estate, 68000 Ampang, Selangor, Malaysia.
Brunei – Zuellig Pharma (B) Sdn Bhd, Unit 5, 1st Floor, Spg 607 Jalan Gadong, Kg Beribi, BE 1118 Bandar Seri Begawan, Brunei Darussalam.
Tel: 673-2652094

21. DATE OF REVISION

16 October 2024

mystory.my@haleon.com
1800 88 3225

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