Voltaren

HALEON

12 Hours Emulgel 2% Gel

12 HRS

Diclofenac diethylamine 23.2mg/g

- Provides 12 hours of uninterrupted targeted pain relief. Penetrates deep to reduce inflammation at the point of pain.
- Relieves pain, inflammation and swelling due to muscle and joints injuries, soft-tissue rheumatism (tendonitis) and arthritis pain.

1. Brand or Product Name

Voltaren 12 Hours Emulgel 2% Gel

2. Name and Strength of Active Substance

One gram of Voltaren 12 Hours Emulgel 2% Gel contains 23.2 mg (2.32% w/w) of diclofenac diethylamine, which corresponds to 20 mg (2% 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 potent 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 12 Hours Emulgel 2% Gel is an anti-inflammatory and analgesic preparation designed for topical application.

In inflammation and pain of traumatic or rheumatic origin, Voltaren 12 Hours Emulgel 2% Gel 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. After topical application of Voltaren 12 Hours Emulgel 2% Gel (2 applications/day) to approximately 400 cm^2 of skin, the extent of systemic exposure as determined by plasma concentration of diclofenac was equivalent to diclofenac diethylamine 1.16% gel (4 applications/day).
The relative bioavailability of diclofenac (AUC ratio) for Voltaren 12 Hours Emulgel 2% Gel versus 50 mg diclofenac sodium tablet was 4.5% on day 7 (for equivalent diclofenac sodium dose). Absorption was not modified by a moisture and vapour permeable bandage.
Voltaren 12 Hours Emulgel 2% Gel formulation contains a permeation enhancer (0.75% oleyl alcohol). In an in vitro skin barrier penetration study, this formulation was compared to Voltaren Emulgel 1.16%, both applied at 20mg/cm^2 in a single dose. The findings demonstrated approximately three times higher cumulative diclofenac skin permeation for Voltaren 12 Hours Emulgel 2% Gel (6.11 ± 1.27 µg/cm^2) compared to Voltaren Emulgel 1.16% (2.07±0.38 µg/cm^2) after 24 hours. These results were reproduced in another study.

Distribution
99.7% of diclofenac is bound to serum proteins, mainly albumin (99.4%).
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.
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
Diclofenac and its metabolites are excreted mainly in the urine.
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.

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

Therapeutic indications
For the relief of pain, inflammation and swelling in the following situations:
- soft-tissue injuries: trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains, bruises and backache (sports injuries);
- localised forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathy;
- 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.

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.

Adults and adolescents aged 12 years and over
Voltaren 12 Hours Emulgel 2% 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 400-800cm^2. After application, the hands should be washed, unless they are the site being treated. Patients should wait until Voltaren 12 Hours Emulgel 2% Gel dries before showering, bathing.
The duration of treatment depends on the indication and clinical response. The product should not be used for more than 14 days for soft-tissue injuries or soft tissue rheumatism, or 21 days for arthritis pain, unless recommended by a doctor.

Children: the product is not recommended for use in children below 12 years.

Elderly patients (over 65 years of age): the usual adult dosage may be used.

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9. Route of Administration

Topical.

10. Contraindications

- Known hypersensitivity to diclofenac or to any of the excipients (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

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.
Keep out of the sight and reach of children.
Topical diclofenac can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
Patients should be instructed to be cautious when smoking or near naked flames due to risk of severe burns. Voltaren 12 Hours Emulgel 2% Gel contains paraffin which is potentially flammable when it builds up on fabric (clothing, bedding, dressings etc.). Washing clothing and bedding may reduce product build up but not totally remove it.

Information concerning excipients
Voltaren 12 Hours Emulgel 2% Gel contains propylene glycol, which may cause mild, localised skin irritation in some people, and butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

Effects on ability to drive and use machines
Topical application of diclofenac 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 unlikely.

13. Statement on Usage during Pregnancy and Lactation

Pregnancy
There are insufficient data on the use of diclofenac in pregnant women. Diclofenac may 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 may lead to birth and baby complications.

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 tabulated below by System Organ Class and frequency. The following convention has been utilised for the classification of undesirable effects: 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 available data). Adverse reactions identified during post-marketing use are reported voluntarily from a population of uncertain size, the frequency of these reactions is not known but likely to be rare or very rare. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Infection and infestation
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 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 50 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

Butylhydroxytoluene
Carbomer
Cocoyl caprylocaprate
Diethylamine
Isopropyl alcohol
Liquid paraffin
Macrogol cetostearyl ether
Oleyl alcohol
Propylene glycol
Perfume eucalyptus sting
Purified water

17. Storage Conditions

Do not store above 30 °C.

18. Packaging

Pack sizes: 30 g, 50 g
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, BE1118,
Bandar Seri Begawan, Brunei Darussalam.

21. Date of Revision

20 May 2025

For Malaysia:
1-800-88-3225
mystory.my@haleon.com

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