SUMMARY OF PRODUCT CHARACTERSTICS

1. NAME OF THE MEDICINAL PRODUCT

Voltaren Emulgel – Diclofenac Diethylamine 1.16g in 100g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3. PHARMACEUTICAL FORM

Emulgel - The base is an emulsion of lipids in an aqueous gel with isopropyl alcohol and propylene glycol added.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of pain, inflammation and swelling for:

· injuries to tendons, ligaments, muscles and joints, e.g. sprains, bruises, strains and back pain after sports or accidents;

· localised forms of soft tissue rheumatism, such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathies;

· and for the symptomatic treatment of arthrosis in small and medium-sized joints close to the skin, e.g. finger joints or knees.

4.2 Posology and method of administration

The product is intended for topical use only.

Adults and adolescents aged 12 years and older

Depending upon the size of the painful or swollen area; an amount ranging in size from a cherry to a walnut will usually be sufficient. Applied to the affected parts of the body 3-4 times a day and rubbed in gently.

The duration of use depends on the indication and the success of the treatment. Reviewing the treatment after two weeks is recommended if the symptoms have not improved. Voltaren Emulgel should not be used for more than 14 days.

After use

The patient should wash their hands after rubbing in Voltaren Emulgel 1%, unless of course they are the site being treated.

Special dosage instructions

Children under 12 years of age

The safety and efficacy of Voltaren Emulgel for use in children under 12 years of age have not been systematically tested. Therefore, it is not recommended for use.

Elderly patients

The normal daily dose for adults can be used.

Patients with hepatic or renal impairment

It is not necessary to adjust the dose due to low systemic availability.

4.3 Contraindications

Do not use in patients with:

Known hypersensitivity to the active substance diclofenac or to any of the excipients (e.g. isopropyl alcohol or propylene glycol; for a complete list see “Composition”).

· For patients in whom acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (such as ibuprofen) trigger asthma attacks, angioedema, urticaria or acute rhinitis.

· During the third trimester of pregnancy (see “Pregnancy, lactation”).

4.4 Special warnings and precautions for use

Voltaren Emulgel should only be applied to intact skin, and not to diseased skin, skin wounds or open injuries.

The eyes and mucous membranes should not come into contact with the product. For topical use only. Do not swallow.

The treatment must be stopped immediately if a skin rash occurs after using the product.

Voltaren Emulgel should not be used with an airtight, occlusive dressing.

If Voltaren Emulgel is used on larger areas of skin and for longer than recommended (see "Dosage/Administration"), the occurrence of systemic undesirable effects cannot be completely excluded. In such cases, the summary of product characteristics for the oral forms of diclofenac should be read.

Information on the excipients

Voltaren Emulgel contains *propylene glycol (E1520))* and *benzyl benzoate.*

Propylene glycol may cause skin irritation. *Benzyl benzoate* may cause localised skin irritation.

Voltaren Emulgel contains *viscous paraffin*. Fabrics (clothing, bedding, dressings, etc.) that have come into contact with the product are more flammable and pose a fire hazard with the risk of severe burns. The patient should be instructed not to smoke or go near open flames when using Voltaren Emulgel. Paraffin is never completely removed from clothing or bed linen, even after washing.

This medicinal product contains a fragrance with linalool, benzyl alcohol, geraniol, citronellol, benzyl benzoate, coumarin, citral and eugenol. These excipients may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the low systemic absorption with topical application, the probability of interactions is very low. See also the last paragraph in the "Warnings and precautions" or "Undesirable effects" section.

4.6. Fertility, Pregnancy and Lactation

Pregnancy

No controlled studies have been conducted on pregnant women. Therefore, Voltaren Emulgel should not be used during pregnancy. Voltaren Emulgel is contraindicated in the third trimester of pregnancy due to possible premature closure of the ductus arteriosus botalli, possible obstruction of labour and possible renal impairment of the foetus, which may progress to renal failure with oligohydramnios.

Animal studies have shown no direct or indirect adverse effects on pregnancy, embryonic/foetal development, birth or postnatal development (see "Preclinical data").

Lactation

It is not known whether diclofenac passes into breast milk when applied topically. Therefore, Voltaren Emulgel should not be used by lactating women. If there is a compelling indication, Voltaren Emulgel should not be used on the chest, over extensive areas of the skin and over a long period of time.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The undesirable effects are listed according to MedDRA system organ classes and frequencies. The undesirable effects are given in decreasing order of severity within each frequency group:

Frequency

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).

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 rash, erythema, eczema, pruritus.

Rare: bullous dermatitis.

Very rare: pustular skin eruption, photosensitisation.

The likelihood of systemic adverse reactions occurring with topical use of diclofenac is low compared to the incidence of adverse reactions with oral treatment with diclofenac.

If Voltaren Emulgel is used on larger areas of skin and for longer than recommended, the occurrence of systemic undesirable effects cannot be completely excluded. In such cases, read the summary of product characteristics for the oral forms of Voltaren.

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.

4.9 Overdose

Due to the low systemic absorption of diclofenac with topical application, an overdose is unlikely.

Undesirable effects similar to those of an overdose with diclofenac tablets are to be expected if Voltaren Emulgel is swallowed (1 tube of 100 g corresponds to 1 g of diclofenac sodium). If significant systemic adverse reactions occur as a result of inappropriate use or accidental ingestion (e.g. in children), the general therapeutic measures commonly used for the treatment of poisoning with non-steroidal anti-inflammatory drugs should be applied.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with pronounced analgesic, anti-inflammatory and antipyretic properties.

Voltaren Emulgel is an anti-inflammatory and analgesic product for external use. The white, cream-like, non-greasy Emulgel is easy to rub into the skin and has a soothing, cooling effect thanks to its aqueous-alcohol base.

The proven inhibition of prostaglandin biosynthesis by diclofenac is considered an important component of its mechanism of action.

In the case of inflammation caused by trauma, Voltaren Emulgel relieves pain and causes regression of oedema.

5.2 Pharmacokinetic properties

Absorption

The amount of diclofenac absorbed through the skin is proportional to the duration of skin contact and the area of skin covered with Voltaren Emulgel and is dependent on the total topical dose and the hydration of the skin. After topical application of 2.5 g Voltaren Emulgel per 500 cm^2 of skin, approximately 6% of the diclofenac dose is absorbed, as determined by total renal elimination compared to Voltaren tablets. Wearing an occlusive dressing for 10 hours increases the absorption of diclofenac threefold.

Distribution

After topical application of Voltaren Emulgel to hand and knee joints, diclofenac is detectable in plasma, synovial tissue and synovial fluid. The maximum plasma concentrations of diclofenac after topical application of Voltaren Emulgel are about 100 times lower than after oral administration of Voltaren tablets. Diclofenac is 99.7% bound to serum proteins, primarily albumin (99.4%).

Metabolism

The biotransformation of diclofenac occurs partly via glucuronidation of the intact molecule, but mainly via single or multiple hydroxylation with subsequent glucuronidation of most of the phenolic metabolites formed in the process. Two of these phenolic metabolites are biologically active, but to a much lesser extent than diclofenac.

Elimination

The total systemic clearance of diclofenac from plasma is 263 ± 56 ml/min (mean ± standard deviation), and the terminal plasma half-life is 1-2 hours. Four of the metabolites, including the two active ones, also have a short plasma half-life of 1-3 hours. One metabolite, 3'-hydroxy-4'-methoxy-diclofenac, has a much longer half-life. However, this metabolite has practically no pharmacological activity. Diclofenac and its metabolites are excreted mainly in urine.

Kinetics in specific patient groups

Renal impairment

In renal insufficiency, accumulation of diclofenac and its metabolites is not expected.

Hepatic impairment

The pharmacokinetics of diclofenac in patients with chronic hepatitis or compensated hepatic cirrhosis are the same as in patients without liver disease.

5.3 Preclinical safety data

Preclinical data based on studies with diclofenac on acute toxicity, repeated dose toxicity, genotoxicity, mutagenicity and carcinogenicity did not indicate any specific hazard to humans at the recommended therapeutic doses. No teratogenic effects were observed in mice, rats and rabbits. Diclofenac has no effect on the fertility of parent animals (rats) or the pre-, peri- and postnatal development of the young.

In various studies, there was no evidence that Voltaren Emulgel causes phototoxicity or skin sensitisation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer, macrogol cetostearyl ether, cocoyl caprylocaprate, diethylamine, isopropyl alcohol, propylene glycol, liquid paraffin, perfume (containing benzyl benzoate), purified water.

6.2 Incompatibilities
None known.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Keep out of the reach and sight of children.
Do not use this medicine after the expiry date ("EXP") stated on the pack.
Do not store above 30ºC.

6.5 Nature and contents of container
Aluminium Laminated Tube

6.6 Special precautions for disposal
No special requirements

7. MARKETING AUTHORISATION HOLDER

World Wide Commercial Ventures Limited,
RC325074, Plot A1 Block 9 Adejumo Estate, Ilupeju Industrial Estate, Lagos, Nigeria.

8. DRUG PRODUCT MANUFACTURER

Haleon Consumer Healthcare SARL
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1260, Nyon
Switzerland

9. NAFDAC REGISTRATION NUMBER

04-0038

10. DATE OF REVISION OF THE TEXT

April 2025