Clean Professional Information

VOLTAREN EMULGEL

SCHEDULING STATUS

20 g, 50 g S0

100 g, 50 ml, 75 ml or 100 ml S1

1. NAME OF THE MEDICINE

Voltaren Emulgel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g Voltaren Emulgel contains 1,16 g diclofenac diethylamine corresponding to 1 g diclofenac sodium.

The base is a fatty emulsion containing isopropanol and propylene glycol, in an aqueous gel.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White gel.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the symptomatic relief of localized traumatic inflammation and pain.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For cutaneous use only.

Voltaren Emulgel 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 (a quantity ranging in size from a cherry to a walnut) is sufficient to treat an area of about 400-800 cm^2.

After application, the hands should be wiped with an absorbent paper towel and then washed, unless they are the site being treated. The absorbent paper towel should be thrown in the trash after use.

Patients should wait until Voltaren Emulgel dries before showering, bathing.

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.

The duration of treatment depends on the indication and the response obtained. It is recommended that treatment be reviewed after 2 weeks.

Population

- **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

- **Hepatic impairment:** the usual adult dosage may be used. *(see section pharmacokinetic)*
- **Renal impairment:** the usual adult dosage may be used *(see section pharmacokinetic)*

Children

Confine use to adults and adolescents aged 12 years and over, as safety and efficacy have not yet been established in children.

4.3 CONTRAINDICATIONS

Hypersensitivity to diclofenac, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs. Hypersensitivity to any other ingredient of the gel.

Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents.

Concomitant use of other products containing diclofenac.

Concomitant use of oral NSAIDs.

Voltaren Emulgel should not be used by patients with porphyria**.**

During the last trimester of pregnancy.

Heart failure.

History of gastrointestinal bleeding or perforation (PUBs) related to previous NSAIDs.

Active or history of recurrent ulcer/haemorrhage/perforations.

4.4 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 Voltaren Emulgel is used at a higher dosage or for longer period of time than recommended (see Dosage and Directions for use).

Voltaren Emulgel contains propylene glycol, which may cause mild, localised skin irritation in some people.

Voltaren Emulgel should be applied only to intact, non-diseased skin surfaces, 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.

Not to be taken by mouth.

Keep out of the sight and reach of children.

Patients should be instructed to be cautious when smoking or near naked flames due to risk of severe burns. Voltaren Emulgel 12 Hour 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.

Occlusion can lead to an increase in the amount of diclofenac absorbed and may thus cause an increase in side-effects.

4.5 INTERACTIONS WITH OTHER MEDICAL PRODUCTS AND OTHER FORMS OF INTERACTION

Interactions as experienced with systemically absorbed diclofenac sodium.

When given concomitantly with lithium, non-steroidal anti-rheumatic agents raise the concentration of lithium in the blood.

The bioavailability of Voltaren is reduced by acetylsalicylic acid, and that of acetylsalicylic acid by Voltaren, when the two drugs are administered together.

4.6 FERTILITY, PREGNANCY AND LACTATION

Fertility

Treatment with Voltaren Emulgel is unlikely to have an adverse effect on fertility because the systemic exposure to diclofenac after application of Voltaren Emulgel is low.

Pregnancy

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations.

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-foetal 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 fetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);

- renal dysfunction, which may progress to renal failure with oligohydroamniosis;
- 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.

Regular use of non-steroidal anti-inflammatory medicines during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in utero, and possibly, in persistent pulmonary hypertension of the new-born.

The onset of labour may be delayed and its duration increased.

Lactation

Diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Voltaren Emulgel, 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, Voltaren Emulgel 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 WARNINGS and SPECIAL PRECAUTIONS).

4.7 UNDESIRABLE EFFECTS

Skin and subcutaneous tissue disorders: Rash, eczema, erythema, pruritus, dermatitis (including dermatitis contact)

Frequent

Skin and subcutaneous tissue disorders: Dermatitis bullous

Less frequent (<1/10 000)

Skin and subcutaneous tissue disorders: Photosensitivity reaction

Infections and infestations: Rash pustular

Immune system disorders: Hypersensitivity (including urticaria), angioedema

Respiratory, thoracic and medicinal disorders: Asthma

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 .

4.8 OVERDOSE

In the event of significant systemic side-effects occurring as a result of improper use or accidental ingestion (e.g., in children), general therapeutic measure of the kind normally adopted in order to treat poisoning with non-steroidal anti-inflammatory drugs should be resorted to.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Topical products for localised traumatic inflammation and pain. Anti-inflammatory preparations, nonsteroids for topical use, ATC code: M02A A15.

Pharmacological classification: A.3.1 Antirheumatic (anti-inflammatory agents)

Mechanism of action and pharmacodynamic effects: Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with pronounced analgesic, anti-inflammatory and antipyretic properties. Inhibition of prostaglandin synthesis is the primary mechanism of action of diclofenac.

Voltaren Emulgel is an anti-inflammatory and analgesic preparation designed for external application. It contains a quantity of active substance equivalent to 1 % diclofenac sodium.

Experimental studies in animals have shown that when applied locally, the active substance penetrates the skin and the underlying tissue, and combats both acute and chronic inflammatory reactions.

Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is regarded as having an important bearing on its mechanism of actions.

5.2 Pharmacokinetics properties

Absorption

The amount of diclofenac absorbed through the skin is relative to the contact time and the area covered with Voltaren Emulgel. Protein binding: 99,7 %.

Elimination

The mean terminal elimination half-life of the unchanged drug is 1 to 2 hours.

Excretion

Diclofenac and its metabolites are excreted mainly in the urine.

The base is a fatty emulsion containing isopropanol and propylene glycol, in an aqueous gel.

Other excipients:

Diethylamine, carbomer 974 P,

Macrogol cetostearyl ether,

Cocoyl caprylocaprate,

Liquid paraffin,

Perfume cream 45,

Purified water.

6.2 SHELF LIFE

Three years.

6.3 SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 °C. Protect the pressurized containers from direct sunlight and do not pierce or burn even when empty.

KEEP OUT OF THE REACH OF CHILDREN.

6.4 NATURE AND CONTENTS OF THE CONTAINER

White gel.

20 g, 50 g and 100 g Aluminium laminated tubes with white or blue polypropylene caps.

Pressurised aluminium 50 ml, 75 ml or 100 ml containers containing a multilayer pouch (low density polyethylene layer in contact with the product) with a high-density polyethylene/titanium oxide valve and polyoxymethylene actuator with protective cap.

Not all pack sizes may be marketed.

7. THE HOLDER OF CERTIFICATE OF REGISTRATION

Haleon SA (Pty) Ltd

11 Hawkins Avenue

Epping Industria 1

Cape Town, 7460

Tel: 011 745 6000

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of registration of the medicine: 16 April 1991

9. DATE OF REVISION OF THE TEXT

27 October 2022

10. REGISTRATION NUMBER

U/3.1/77

Additional countries registration details:

Country	**Scheduling status (or Category of distribution)**	**Registration no.**
Botswana	S3	B9305535
Namibia	NS1	04/3.1/0344
Zambia	POM	242/015
Zimbabwe	P	87/3.1/2128

ATC Code: M02AA15 – Anti-inflammatory preparations, non-steroids for topical use

Pharmacological classification: 3.1 – Nonsteroidal anti-inflammatory medicines (Zimbabwe)

Name and address of manufacturer:

Haleon SARL

Route de l'Etraz 2, CH-1260, Nyon, Switzerland

Or

Purna Pharmaceuticals NV

Rijksweg 17,

B-2870 Puurs, Belgium