1. NAME OF THE MEDICINAL PRODUCT

Voltaren Emulgel 1 % gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of Voltaren Emulgel contains 11.6 mg of the active substance diclofenac diethylamine, which corresponds to 10 mg of diclofenac sodium. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel for topical administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Self medication for the following indications:
Local treatment of pain, inflammation and swelling due to:

- Pain and inflammation and swelling in trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and/or bruises and/or backache (e.g. sports injuries);
- Localized forms of soft tissue rheumatism such as tendonitis (e.g. tennis elbow), bursitis.

By Physicians order:

- Pain caused by osteoarthritis of the peripheral joints, as of the knee or fingers.

4.2. Posology and method of administration

Adults and adolescents aged 12 years and over:

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 washed, unless they are the site being treated.

The duration of treatment depends on the indication and clinical response. The gel should not to be used for more than 14 days for soft-tissue injuries or soft tissue rheumatism unless recommended by a doctor, or 21 days for arthritis pain

When used without medical prescription, patients should consult their doctor if the condition does not improve within 7 days, or if it gets worse.

Children:

Voltaren Emulgel is not recommended for use in children below 12 years of age.

The elderly:

The usual adult dosage may be used.

4.3. Contraindications

- Patients with or without chronic asthma in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Hypersensitivity to diclofenac, acetylsalicylic acid or non-steroidal anti-inflammatory drugs or any of the excipients listed in section 6.1.

- Third trimester of pregnancy.
- Concomitant use of oral NSAID's
- Voltaren Emulgel should not be co-administered with other products containing diclofenac.
- The use in children and adolescents aged less than 12years is contraindicated.

4.4. Special warnings and precautions for use

The possibility of systemic adverse events from application of Voltaren Emulgel cannot be excluded if the preparation is used on large areas of skin and over a prolonged period (see the product information on systemic forms of diclofenac). Voltaren Emulgel 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.

Patients with a history of, or active, peptic ulceration. Some possibility of gastro- intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

Like other drugs that inhibit prostaglandin synthetase activity, diclofenac and other NSAIDs can precipitate
bronchospasm if administered to patients suffering from or with a previous history of asthma or allergic disease.
Voltaren Emulgel contains propylene glycol, which may cause mild, localised skin irritation in some people.

Voltaren Emulgel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

The product contains alcohol. Do not light a cigarette or expose yourself to fire until the gel is completely dried

4.5. Interactions with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from a topical application of Voltaren Emulgel is very low, such interactions are very unlikely. There are no known interactions with Voltaren Emulgel but for a list of interactions known with oral diclofenac the Summary of Product Characteristics for oral dosage forms should be consulted.

Concurrent use of aspirin or other NSAIDs may result in an increased incidence of adverse reactions

4.6. Fertility, Pregnancy and lactation

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/fetal 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 fetal 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 antiaggregating 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.

Rarely, the use of nonsteroidal anti-inflammatory drugs (NSAIDs) after 20 weeks gestation in pregnancy may cause fetal renal dysfunction leading to oligohydramnios.
These effects are seen after days to weeks of treatment. Although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.
The use of NSAIDs after week 20 of gestation should be restricted. If the benefit of NSAID treatment is considered greater than the risk, limit use to the lowest effective dose and shortest duration possible.
Consider ultrasound monitoring of amniotic fluid if NSAID treatment of this medicine at the full treatment dosage extends beyond five days. Discontinue the NSAID if oligohydramnios occurs.

Lactation

Like other NSAIDs, 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 section 4.4).

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common (>1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000), Not known: cannot be estimated from the available data.

Table 1

Immune system disorders	
Very rare:	Hypersensitivity (including urticaria), angioneurotic oedema.
Infections and infestations	
Very rare:	Rash pustular.
Respiratory, thoracic and mediastinal disorders	
Very rare:	Asthma.
Skin and subcutaneous tissue disorders	
Common:	Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus.
Rare:	Dermatitis bullous.
Very rare:	Photosensitivity reaction.

General: Systemic absorption of this medicine is low compared with plasma levels obtained following administration of oral forms of Voltaren Emulgel and the likelihood of systemic side-effects occurring with topical diclofenac is small compared with the frequency of side-effects associated with oral diclofenac. However, where Voltaren Emulgel is applied to a relatively large area of skin and over a prolonged period, the possibility of systemic side-effects cannot be completely excluded. If such usage is envisaged, the data sheet on Voltaren oral dosage forms should be consulted.

Reporting of suspected adverse reactions

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. Any suspected adverse events should be reported to the Ministry of Health according to the
National Regulation by using an online form
(http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il).
Additionaly, please also report to GSK Israel (il.safety@gsk.com)

4.9. Overdose

Signs and symptoms

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 Voltaren Emulgel is inadvertently ingested (1 tube of 100 g contains the equivalent of 1000 mg 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. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from Diclofenac overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal irritation, and respiratory depression; specific therapies such as forced

diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

This medicine is an anti-inflammatory and analgesic preparation designed for external application Due to an aqueous-alcoholic base the gel exerts a soothing and cooling effect.

5.2. Pharmacokinetic properties

When Voltarol Emulgel is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Voltaren Emulgel.

Synovial fluid and tissue levels of diclofenac are higher than those detected in plasma.

5.3. Preclinical safety data

None known.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Purified water, Isopropyl alcohol, Propylene glycol (1,2 Propylene glycol, dist.), Liquid paraffin Mineral Oil (Liquid Paraffin, heavy), Cocoyl caprylocaprate (Cetiol LC), Macrogol cetostearyl ether (Cetomacrogol 1000), Carbomers (Carbopol 974 P), Diethylamine, Perfume Cream 45.

6.2. Incompatibilities

None Stated.

6.3. Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 30°C.

This medicine should be kept out of the sight and reach of children.

6.5. Nature and contents of container

Aluminium tube sealed with membrane (aluminium seal), lined inside with an epoxy phenol resin lacquer with Polypropylene screw cap with built in point to pierce aluminium seal.

Pack sizes:10, 20, 30, 50, 100, g.

Aluminium laminated tube from outside to inside: low density polyethylene/ aluminium/ high density polyethylene with shoulder of high density polyethylene with polypropylene screw cap blue or white

Pack sizes: 20, 30, 50, 100, 150 g..

Aluminium laminated tube from outside to inside: low density polyethylene/ aluminium/ high density polyethylene, with shoulder made of high density polyethylene. With push/ pull cap from white HDPE head (two components inner and outer), orange polypropylene (PP) body and a non-coloured PP over-cap

Pack sizes: 120 g Not all pack sizes may be marketed

6.6. Instructions for use/handling

No special requirements.

7. MANUFACTURER

Novartis Consumer Health SA, Nyon, Switzerland

8. License Holder and Importer

GSK Consumer Healthcare Israel LTD., P.O.B 3256, Petach Tikva.,

8. LICENSE NUMBER(S)

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