1. Name of the medicinal product

EVERFENAC GEL (Diclofenac Diethylamine, Methyl Salicylate, Linseed oil, & Menthol gel)

2. Qualitative and quantitative composition

Composition:

Diclofenac Diethylamine BP	1.16% w/w
Eq. to Diclofenac sodium	1.00% w/w
Methyl Salicylate BP	10.00% w/w
Linseed oil BP	3.00% w/w
Menthol BP	5.00% w/w
Benzyl Alcohol BP	1.00% w/w
(As Preservative)	
Gel Base	Q.S.

For the full list of excipients see, section 6.1

3. Pharmaceutical form

Topical. White coloured smooth gel in a 30gm laminated tube

4. Clinical particulars

4.1 Therapeutic indications

For the local symptomatic relief of pain and inflammation in:

- Trauma of the tendons, ligaments, muscles and joints, eg due to sprains, strains and bruises
- localized forms of soft tissue rheumatism

4.2 Posology and method of administration

For cutaneous use only

Adults and children 14 years and over: It should be rubbed gently into the skin. Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) of gel should be applied 3 - 4 times a day.

After application, the hands should be washed unless they are the site being treated.

Use in the elderly: The usual adult dosage may be used.

Children and adolescents: There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age.

In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

It is suitable for the transmission of ultrasound and may be used as a couplant in combination with ultrasound therapy. If large areas of the body are covered with gel, systemic absorption will be greater and the risk of side-effects increased, especially if the therapy is used frequently.

4.3 Contraindications

• Patients with or without chronic asthma in whom asthma, angioedema, urticaria or acute rhinitis are precipitated by acetylsalicylic acid (aspirin) or other non- steroidal anti-inflammatory drugs (NSAIDs).

• Hypersensitivity to diclofenac or any of the excipients

• Third trimester of pregnancy.

• The use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warnings and precautions for use

Concomitant use of systemic NSAIDs should be cautioned since the possibility of an increase in incidence of untoward effects, particularly systemic side effects, cannot be ruled out.
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, bronchial asthma.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects
The most commonly observed side effects were nausea, diarrhea, hypersensitivity, anaphylactic shock, vomiting etc.

4.9 Overdose
Signs and symptoms

The low systemic absorption renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if is inadvertently ingested (e.g. 1 tube of 100g contains the equivalent of 1000mg of diclofenac sodium).

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal 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.

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. The use of activated charcoal should be considered, especially within a short time (within one hour) of ingestion of a toxic dose.

5. Pharmacological properties

5.1 Pharmacodynamic properties
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).

5.2 Pharmacokinetic properties
It 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. From the skin and underlying tissue, diclofenac preferentially distributes and persists in deep inflamed tissues (such as the joint), rather than in the bloodstream.

5.3 Preclinical safety data
None known

6. Pharmaceutical particulars

6.1 List of excipients

Benzyl Alcohol
Linseed oil
Capsaicin
Menthol
Cresol
Sodium methyl hydroxy benzoate
Sodium propyl hydroxyl benzoate
Carbomer
Isopropyl alcohol
Propylene glycol
Sodium hydroxide flakes

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C. Do not freeze.

6.5 Nature and contents of container

30 gm tube packed in monocarton with leaflet. Such 10 monocarton in a outer carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT / MANUFACTURER

MANUFACTURER

Lesanto Laboratories
Plot No. 9, 10, 11 & 20, Survey no.53,Manor road,
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APPLICANT

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