SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

Diclofen Emulgel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Diclofenac sodium 1.0 % (as Diclofenac diethyl ammonium)
For excipients, see 6.1.

3. PHARMACEUTIC FORM

Emulgel

4. CLINICAL DATA

4.1. *THERAPEUTIC INDICATIONS*

For the local symptomatic relief of pain and inflammation in:
- trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and ruises
- localized forms of soft tissue rheumatism

For the relief of pain of non-serious arthritic conditions

4.2. *POSOLOGY AND METHOD OF ADMINISTRATION*

Gel for topical administration.
For cutaneous use only
Adults and children 14 years and over: diclofenac Emulgel 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.
Diclofenac sodium Emulgel 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 SPECIAL PRECAUTIONS FOR USE*

The possibility of experiencing systemic adverse events (those associated with the use of systemic forms of diclofenac) from application of diclofenac sodium Emulgel cannot be excluded if the preparation is used at higher dosage/large amounts over large areas of skin and over a prolonged period (see the product information on systemic forms of diclofenac e.g. oral or injection for systemic adverse reactions).

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.

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

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.

Diclofenac sodium 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 should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.

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

Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5. *INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS*

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

4.6. *USE DURING PREGNANCY AND LACTATION*

Fertility

There are no data available on the use of topical formulations of diclofenac and its effects on fertility in humans.

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 oligo-hydroamniosis;

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.

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of diclofenac sodium 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, diclofenac sodium 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.

4.7. *EFFECTS ON ABILITY TO DRIVE AND USE MACHINES*

Cutaneous application of diclofenac sodium 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 disorder:	
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
Not known:	Desquamation, skin discolouration

4.9. OVERDOSE

Signs and symptoms

The low systemic absorption of diclofenac sodium Emulgel renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if diclofenac sodium Emulgel 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 Voltarol 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. PHARMACODYNAMICS PROPERTIES

Pharmacotherapeutic group: Topical products for joint and muscular pain, anti- inflammatory preparations, non-steroids for topical use (ATC code M02A A15).

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).

This medicine is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and pain of traumatic or rheumatic origin, relieves pain and decreases swelling.

Due to an aqueous-alcoholic base the gel exerts a soothing and cooling effect.

5.2. PHARMACOKINETIC PROPERTIES

When diclofenac sodium 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 diclofenac sodium Emulgel. From the skin and underlying tissue, diclofenac preferentially distributes and persists in deep inflamed tissues (such as the joint), rather than in the bloodstream.

After topical administration of diclofenac sodium Emulgel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of diclofenac sodium emulgel.

5.3. Preclinical safety data

None

6. PHARMACEUTICAL DATA

6.1. LIST OF EXCIPIENTS

Titriplex III E.D.T.A, Methyl paraben, Propyl paraben, Propylene glycol, Carbopol (940), Water bidistilled, Isopropyl alcohol, Isopropyl Myristate, fragrance, and Triethanolamine

6.2. INCOMPATIBILITIES

None

6.3. SHELF-LIFE

3 years

6.4. SPECIAL PRECAUTIONS FOR STORAGE

- Store between 15°C – 25 °C.
- Protect from heat.
- Keep this medicine and all other medicines out of the reach of children

6.5. NATURE AND CONTENT OF CONTAINER

1 Aluminum tube of 30 or 60 g per carton box including a leaflet.

6.6. INSTRUCTIONS FOR USE AND HANDLING, AND DISPOSAL

None

7. MARKETING AUTHORIZATION HOLDER

Jerusalem Pharmaceuticals Co. Ltd
Al-Bireh, Ramallah, West Bank, Palestine.
P.O. Box 3570
Tel : 0097022406550 / Fax: 0097022403246

8. MRKETING AUTHORISATION NUMBER(S):

Diclofen Emulgel: **003/4101/30**

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization:
17/11/1990

Date of renewal of the authorization: Not applicable

10. DATE OF REVISION OF THE TEXT

30/05/2021

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Very rare:	Photosensitivity reaction
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5.3. Preclinical safety data

None

6. PHARMACEUTICAL DATA

6.1. LIST OF EXCIPIENTS

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6.2. INCOMPATIBILITIES

None

6.3. SHELF-LIFE

3 years

6.4. SPECIAL PRECAUTIONS FOR STORAGE

- Store below 30°C.
- Keep this medicine and all other medicines out of the reach of children

6.5. NATURE AND CONTENT OF CONTAINER

1 Aluminum tube of 30 or 60 g per carton box including a leaflet.

6.6. INSTRUCTIONS FOR USE AND HANDLING, AND DISPOSAL

None

7. MARKETING AUTHORIZATION HOLDER

Jerusalem Pharmaceuticals Co. Ltd
Al-Bireh, Ramallah, West Bank, Palestine.
P.O. Box 3570
Tel : 0097022406550 / Fax: 0097022403246

8. MRKETING AUTHORISATION NUMBER(S):

09351/09290/NMR/2021

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization:
Dec 23, 2023

Date of renewal of the authorization: Not applicable

10. DATE OF REVISION OF THE TEXT

01/04/2023