Lisodim Emulgel

(Diclofenac Gel BP)

لائیسوڈم ایمل جل

(ڈائیکلوفینک جل بی پی)

COMPOSITION: Each gram gel contain:
Diclofenac diethylamine BP ... 11.6mg (1.16%)
(Corresponds to 10mg Diclofenac Sodium) [BP Specs.]

DESCRIPTION: Lisodim Emulgel contains the active substance Diclofenac which belongs to a group of medicines called non-steroidal antiinflammatory drugs (NSAIDs). It is specially formulated for rubbing into the skin and used to relieve pain and reduce inflammation and swelling in painful conditions affecting the joints and muscles.

CLINICAL PHARMACOLOGY: Mechanism of Action: 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.

PHARMACOKINETICS: When **Diclofenac Diethylamine 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 Diethylamine 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 Diethylamine 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 Diethylamine Emulgel**.

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.
- Localised forms of soft tissue rheumatism.

It is recommended that the treatment be reviewed after 14 days in these indications. For the treatment of osteoarthritis of superficial joints such as the knee. In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks.

DOSAGE AND ADMINISTRATION: For cutaneous use only.
Adults and children 14 years and over: Diclofenac Diethylamine 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. 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.
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 ultrasound: Lisodim 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.

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.

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WARNINGS AND PRECAUTIONS: The possibility of experiencing systemic adverse events (those associated with the use of systemic forms of Diclofenac) from application of **Diclofenac Diethylamine 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. 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 Diethylamine 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 Diethylamine Emulgel** can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing. 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.

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: 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. 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 Diethylamine 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 Diethylamine 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.

SIDE EFFECTS: Common side effects includes rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus.

DRUG 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 Diethylamine Emulgel**, but for a list of interactions known with oral Diclofenac the data sheet for oral dosage forms should be consulted.

OVERDOSE: Signs and symptoms: The low systemic absorption of **Diclofenac Diethylamine Emulgel** renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of Diclofenac tablets, can be expected if **Diclofenac Diethylamine 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 Diclofenac 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.

INSTRUCTIONS: Store below 30°C. Protect from heat and light. Keep out of the reach of children.

PRESENTATION: Lisodim Emulgel is available in pack size of 20g.

ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

PHARMA
Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
17/24, Korangi Industrial Area, Karachi-Pakistan.

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