

TRAVO 1% Gel

[Diclofenac Diethylamine]

ٹراوو ۱% جیل

DESCRIPTION:

TRAVO (Diclofenac) is a topical product for joint and muscular pain, anti-inflammatory preparations, non-steroids for topical use.

QUALITATIVE AND QUANTITATIVE COMPOSITION:

TRAVO (Diclofenac) is available for topical administration as:

TRAVO 1% Gel

Each gram contains:

Diclofenac Diethylamine BP 11.6mg equivalent to Diclofenac

Sodium.....10 mg (1% w/w)

(Product Specs.: BP)

CLINICAL PHARMACOLOGY:

Mechanism of Action:

Diclofenac, the active substance of TRAVO Gel, is an NSAID with pronounced anti-rheumatic, anti-inflammatory, analgesic, and antipyretic properties.

Inhibition of prostaglandin biosynthesis by diclofenac has been demonstrated experimentally and is regarded as an important component of its mechanism of action.

PHARMACOKINETICS:

Absorption:

The amount of diclofenac absorbed through the skin is proportional to the contact time and skin area covered with TRAVO Gel, topical dose and the hydration of the skin.

Distribution:

After topical administration of TRAVO Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue, and synovial fluid. Maximum plasma concentrations of diclofenac after topical administration are about 100 times lower than after oral administration of diclofenac tablets. 99.7% of diclofenac binds to serum proteins, chiefly to albumin (99.4%).

Metabolism:

Metabolism of diclofenac involves partly glucuronidation of the intact molecule, but mainly single and multiple hydroxylation resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, however, to a much smaller extent than diclofenac.

Elimination:

Diclofenac and its metabolites are excreted mainly in the urine. The terminal plasma half-life is 1 to 2 hours.

Special Populations:

- No accumulation of diclofenac or its metabolites is to be expected in patients suffering from renal impairment.
- The kinetics and metabolism of diclofenac are the same in patients with chronic hepatitis or non-decompensated cirrhosis, as in patients without liver disease.

THERAPEUTIC INDICATIONS:

TRAVO (Diclofenac) Gel is indicated for the treatment of:

- Post-traumatic inflammation of the tendons, ligaments, muscles, and joints, e.g. due to sprains, strains, and bruises.
- Localized forms of soft-tissue rheumatism, e.g. tendovaginitis, bursitis, shoulder-hand syndrome, and periartropathy.
- Localized forms of degenerative rheumatism, e.g. osteoarthritis of the peripheral joints and vertebral column.

DOSEAGE AND ADMINISTRATION:

- TRAVO Gel is applied locally to the skin 3 or 4 times daily and rubbed gently. The amount needed depends on the size of the painful site. The duration of treatment depends on the indication and the response obtained. It is recommended that treatment be reviewed after 2 weeks.
- Do not use on open or cut wounds.

Special Populations:

Pediatrics Patients:

Dosage recommendations and indications for the use of TRAVO Gel in children have not been established.

Geriatrics (Patients aged 65 or above):

Same dosage used in Geriatrics.

CONTRAINDICATIONS:

- Known hypersensitivity to the active substance.
- TRAVO Gel is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.

WARNINGS AND PRECAUTIONS:

- The likelihood of systemic side effects with topical diclofenac is small, compared with the frequency of side effects in patients using oral diclofenac. However, when Diclofenac Gel is applied to relatively large areas of skin over a prolonged period of time, the possibility of systemic side effects cannot be excluded. In case such usage is planned, the product information on systemic forms of diclofenac should be consulted.
- TRAVO Gel should be applied only to healthy and intact skin surfaces (those without open wounds or injuries). Contact with the eyes or with mucous membranes should be avoided. TRAVO Gel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
- TRAVO Gel should not be ingested.

DRUG INTERACTIONS:

Since systemic absorption of diclofenac from topical application is very low, interactions are very unlikely.

Pregnancy:

Not recommended for use during pregnancy.

Lactation:

It is not known whether topical diclofenac is excreted in human milk, and TRAVO Gel is therefore not recommended during breast-feeding. If there are compelling reasons for using TRAVO Gel during breast-feeding, it should not be applied to the breast or to large areas of skin, nor should it be used for a prolonged period.

ADVERSE REACTIONS:

Infections and infestations:

Very rare: Pustular rash.

Immune system disorders:

Very rare: Hypersensitivity (including urticaria), angioedema.

Respiratory, thoracic and mediastinal disorders:

Very rare: Asthma.

Skin and subcutaneous tissue disorders:

Common: Dermatitis (including contact dermatitis), rash, erythema, eczema, pruritus.

Rare: Bullous dermatitis.

Very rare: Photosensitivity reaction.

OVERDOSE:

The low systemic absorption of topical diclofenac makes an overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if diclofenac gel is inadvertently ingested. General supportive measures and symptomatic treatment should be employed as in other cases of intoxication with non-steroidal anti-inflammatory medicines. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

INSTRUCTIONS:

- Store between 15°C - 30°C.
- Protect from light & freezing.
- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED:

TRAVO (Diclofenac) 1% Gel is available in a 20g aluminum tube.

خبردار: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
دوا کا نام: ٹراوو ۱% جیل ہے۔ اس کی بوتلی کے گرد بیان میں رکھیں۔
دیکھیں اور تجدد ہونے سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
احتیاط: صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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