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21mmPRESCRIBING INFORMATION LEAFLET
Dicloran Gel 2%

For the use of Registered Medical Practitioner, Hospital or Laboratory only

ANTI-INFLAMMATORY & ANALGESIC GEL

DICLORAN® Gel 2%

COMPOSITION:

Diclofenac Diethylamine IP 2.32% w/w
(Equivalent to Diclofenac Sodium 2.00% w/w)
Linseed Oil BP 3.00% w/w
Methyl Salicylate IP 10.00% w/w
Menthol IP 5.00% w/w
Benzyl Alcohol IP 1.00% w/w
(As Preservative)
Gel Base q.s.

DOSAGE FORM:

DICLORAN GEL 2% is available in gel form for topical application.

INDICATIONS AND USAGE:

DICLORAN GEL 2% is indicated for symptomatic relief of mild to moderate pain and inflammation associated with:

- trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains and bruises
- localised forms of soft tissue rheumatism

DOSAGE AND ADMINISTRATION:

DICLORAN GEL 2% is for external use only and not to be administered orally. It should not be applied on any mucosa, open wound, cut or diseased skin. Patient should be advised that the site of application is clean and dry before application of DICLORAN GEL 2%. Depending on the size of the affected site to be treated 2-4g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 2 times daily (preferably morning and evening). The maximum daily dose is 8g. Therefore the maximum weekly dose is 56g.

The treatment may be discontinued when the symptoms (pain and swelling) have subsided. For acute painful musculoskeletal conditions, patient should be advised to consult the doctor, if no improvement is seen within 3 days. Treatment should not be continued beyond 7 days without review for acute painful musculoskeletal conditions. For arthritis pain, if symptoms do not improve within day 7 or if they worsen, a consultation with doctor is recommended and use for more than 14 days is not recommended without review in Arthritis pain.

USE IN SPECIAL POPULATION:

Use in pregnancy: no data is available for use of DICLORAN GEL 2% in pregnant women. During the first and second trimester of pregnancy, DICLORAN GEL 2% should not be given unless the benefit outweighs the risk. DICLORAN GEL 2% is contraindicated during the third trimester of pregnancy. Use during Lactation: No data is available for use of DICLORAN GEL 2% in breast-feeding women. However, NSAIDS are excreted in human milk. Therefore DICLORAN GEL 2% is not recommended for use in breast-feeding mothers.

Paediatric Use: Use in Paediatric population is not recommended as data related to safety and efficacy is not available.

Geriatric Use: No overall difference in effectiveness or safety is expected between elderly and younger patients, but because elderly patients are more likely to have decreased renal function, care should be taken when using DICLORAN GEL 2% in the elderly and it may be useful to monitor renal function.

CONTRAINDICATIONS:

Hypersensitivity to the active substances, any of the excipients, acetyl salicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDS). Patients with asthma or in patient when attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other NSAID. Children and adolescents less than 14 years.

During the last trimester of pregnancy, Breast-feeding mothers, Patient who has undergone Coronary Artery Bypass Graft (CABG) surgery in the past 2 weeks.

WARNING AND PRECAUTIONS:

Contact of DICLORAN GEL 2% with eyes or mucous membrane should be avoided and it should not be ingested. DICLORAN GEL 2% is not recommended for occlusive dressing. Photosensitivity reactions have been reported with topical use of diclofenac. Patients should be warned against exposure to sunlight after application of DICLORAN GEL 2%. Discontinue the treatment if rash appears after application. The concomitant use of DICLORAN GEL 2% with oral NSAIDS should be cautioned as the incidence of undesirable systemic effects may increase. DICLORAN GEL 2% should be used with caution in patients with history of peptic ulcer, hepatic or renal insufficiency, bleeding diathesis or inflammatory bowel disease as isolated incidence of such cases with topical diclofenac have been reported. Do not mix or apply DICLORAN GEL 2% with any other topical agent.

DRUG INTERACTIONS:

When used as per recommended dosage, the systemic availability of topical diclofenac from DICLORAN GEL 2% is very low as compared to an oral formulation of diclofenac. Hence the risk of interactions with other oral medicinal products is reduced. Concurrent acetylsalicylic acid or other NSAIDs may result in an increased incidence of adverse reactions.

UNDESIRABLE EFFECTS:

Topical application of diclofenac may be associated with local adverse effects at the site of application.

Skin: Local irritation, pruritis, burning sensation, rash, eczema, erythema (including rare cases erythema bullosum). Urticaria, contact dermatitis, contact dermatitis with vesicles etc., isolated cases of generalised skin rash, hypersensitivity reactions such as angioedema, anaphylactic reactions and photosensitivity reactions have been reported in patients using topical NSAID preparations.

OVERDOSE:

The low systemic bioavailability of diclofenac from DICLORAN GEL 2% makes overdose very unlikely.

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties: Diclofenac inhibits the cyclooxygenase (COX) enzyme, an early component of the arachidonic acid cascade, resulting in the reduced formation of prostaglandins, thromboxanes and prostacyclin. Diclofenac, the active component has anti-inflammatory, anti-nociceptive and antipyretic effects. Methyl salicylate is a salicylic acid derivative and acts as rubefacient.

Topical application leads to pain relief in musculoskeletal, joint and soft tissue disorders by its counter irritant action. Menthol dilates the blood vessels causing a sensation of coldness, followed by an analgesic effect. Menthol also acts as a penetration enhancer, increasing the penetration of the drug when applied on the skin, to give faster onset of action.

Pharmacokinetic Properties:

Absorption:

The quantity of diclofenac absorbed through the skin is proportional to the size of the treated area, and depends on both the total dose applied and the degree of skin hydration.

Distribution: Diclofenac is more than 99% bound to human serum proteins, primarily to albumin. Diclofenac diffuses into and out of synovial fluid.

Metabolism: The major diclofenac metabolite 4'hydroxy-diclofenac, has very weak pharmacological action. The formation of 4'hydroxy-diclofenac is primarily mediated by CYP2C9. Both diclofenac and its metabolite undergo glucuronidation or sulfation followed by biliary excretion. CYP3A4 is responsible for the formation of minor metabolites, 5 hydroxy and 3'hydroxy-diclofenac.

Elimination: Diclofenac is eliminated through urinary and biliary excretion of the glucuronide and the sulphate conjugates of the metabolites. Little or no free unchanged diclofenac is excreted in the urine.

INCOMPATIBILITIES:

Do not mix or apply it with any other topically applied medicine or any herbal preparations.

PACKAGING INFORMATION:

Available in 30gm & 10gm Laminite

STORAGE AND HANDLING:

Store in a cool place. Do not freeze. Protect from light. Keep out of reach of children.

WARNING: Not for veterinary use.

Manufactured in India by :

Lekar Pharma Ltd.

At : Plot No. 304-308, G.I.D.C. Industrial Area, Panoli - 394 116.

® Regd. Trade Mark

Marketed by:

Lekar Pharma Ltd.

Neelam Centre, B' Wing, 3rd Floor,

Hind Cycle Road, Worli, Mumbai - 400 030, India

PATIENT INFORMATION LEAFLET
Dicloran Gel 2%

How to use DICLORAN GEL 2%?

Always use this medicine exactly as described in this leaflet. You should check with your doctor if you are not sure.

How much DICLORAN GEL 2% to use?

For adults and adolescents 14 years and above.

Apply the gel 2 times a day (preferably morning and evening) on the painful area.

How to apply DICLORAN GEL 2%?

1. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area, slowly rubbing into the skin. The amount needed will vary depending upon the size of the painful or swollen area. You may notice a slight cooling effect when you rub the gel. Only use the smallest amount of DICLORAN GEL 2% needed to relieve your pain but never use more than 8g per day and 56g in one week.

2. Unless the hands are the site being treated, wash your hands after rubbing the gel, to avoid accidental contact with mouth and eyes. DICLORAN GEL 2% is for external use only.

How long to use DICLORAN GEL 2% for?

Do not use DICLORAN GEL 2% for more than 7 days unless longer treatment is recommended by doctor. If the pain and swelling do not improve within 7 days, or if they worsen, consult your doctor. In children aged 14 years and above, if this product is required for more than 7 days for pain relief or if the symptoms worsen, the patient/parents of the adolescent/s are advised to consult a doctor.

If you use more than recommended DICLORAN GEL 2%, then what should you do?

- If you use more gel then you should wipe off the surplus gel with a tissue paper.
- If you or a child accidentally swallows the gel, contact your doctor immediately.

If you forget to use DICLORAN GEL 2%?

If you miss your application of DICLORAN GEL 2% at the correct time, apply it when you remember and then carry on as normal. Do not apply a double quantity to make up for the forgotten application. If you have any further questions on the use of this product, ask your doctor.

Possible side effects

Like all medicines, DICLORAN GEL 2% can cause side effects, although not everybody gets them.

If you experience any of the following signs of allergy, STOP using DICLORAN GEL 2% and tell the doctor immediately:

Skin rash with blisters, Hives, Wheezing, Shortness of breath or feeling of tightness in the chest (asthma).

Common side effects

Skin rash, itching, reddening or smarting of the skin.

Very rare side effects

The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

If you get any side effects which worry you (even side effects not listed in this leaflet), talk to your doctor.

How to store DICLORAN GEL 2%?

Keep this medicine out of the reach and sight of children.

Do not use DICLORAN GEL 2% after the expiry date which is stated on the carton and tube.

Store in a cool place. Do not freeze.

Do not dispose of medicines via wastewater or household waste.

What is in the pack and further information?

What DICLORAN GEL 2% contains?

The active substance is Diclofenac Diethylammonium. Each gram of gel contains 23.2mg of Diclofenac Diethylammonium.

What DICLORAN GEL 2% looks like?

DICLORAN GEL 2% is a white to practically white, cooling, non-greasy, non-staining cream-like gel.

The product comes in pack of 30g lami tube.

रोगी सुचना पत्र

धायकलोरान जैल 2% का प्रयोग कैसे करें?

इस दवा का प्रयोग सदैव उसी तरह से करें जिस तरह से करने के लिए इस लीफलैट में बताया गया है। यदि आप आश्वस्त नहीं हैं तो आपको चाहिए कि आप अपने डॉक्टर से पूछ लें।

धायकलोरान जैल 2% कितनी प्रयोग में लानी है?

वयस्कों और १४ वर्ष से अधिक आयु वाले किशोरों के लिए, दर्द वाली जागह पर दिन में दो बार (हो सके तो सुबह और शाम के समय) जैल लगाएं।

धायकलोरान जैल 2% किस तरह से लानी है?

१. हाले से थोड़ी सी जैल ट्यूब से निकालें और दर्द या सूजन वाली जागह पर लगाएं, त्वचा पर दिसे हल्के हाथ से भरें। दर्द या सूजन कितनी जगह में है इस पर निकालें। कितनी मात्रा दर्द वाली जागह पर लगाएं। धायकलोरान जैल 2% की यथावश्यक न्यूनतम मात्रा ही दर्द से राख पाने के लिए प्रयोग १४ वर्ष से लाएं तिक्तु प्रतिदिन ८ ग्राम और एक सालाह में ५६ ग्राम से अधिक आयु के प्रयोग कभी न करें।

२. केन्द्र पर जब तक कीरी और द्वारा उपचार न किया जा रहा हो तो गलती से मुँह और अंगूठे में चले जाने से बचने के लिए जैल मलने के बाद आप अपने हाथ धो लें।

धायकलोरान जैल 2% का प्रयोग कैसे किया है?

जब तक डॉक्टर न रहे तब तक ७ दिन से अधिक समय तक आप धायकलोरान जैल 2% का प्रयोग न करें। ५ दिनों में यदि दर्द और सूजन में सुधार नहीं आता है तो या पिर यह बिंगड़ा जा रहा है तो अपने डॉक्टर से सलाह लें। १४ वर्ष या इससे अधिक आयु के बच्चों के लिए यह इस दिन से अधिक की पड़े या लक्षण बिंगड़ा जाएं तो जब याद आए आप इसे तब लगा लें और किसे पौछें।

यदि आपने धायकलोरान जैल 2% का प्रयोग संस्कृत से अधिक कर लिया हो तो आपको क्या करना चाहिए?

- यदि आपने आवश्यकता से अधिक जैल का प्रयोग कर लिया हो तो आप इस अनावश्यक जैल को टिशू से पौछें।
- गलती से यदि आपने यह निकाल लिया हो तो आप तक्ताल डॉक्टर से संपर्क करें।

यदि आप अपने डॉक्टर से धायकलोरान जैल 2% का प्रयोग करना भूल गए हों तो?

यदि आप सही समय पर धायकलोरान जैल 2% लगाना भूल गए तो जब याद आए आप इसे तब लगा लें और किसे पौछें। लगाना भूलने की वजह से आप इसे दुरुनी मात्रा में लगाएं। इस उत्पाद पर यदि आप के कोई और प्रश्न हैं तो आप अपने डॉक्टर की सलाह लें।

संभावित दुष्प्रभाव