Front

DICLORAN*GEL
Diclofenac Gel BP

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DICLORAN the brand of Diclofenac, is an anti-inflammatory and analgesic agent.

Composition:
Each gram of gel contains:
Diclofenac Diethylamine BP.....11.6 mg
Equivalent to Diclofenac Sodium.....10 mg
in water soluble gel base
with propylene glycol.....q.s.

Description
White to off white opalescent smooth gel.

Pharmacodynamics
1. Dicloran gel is an anti-inflammatory and analgesic preparation designed for external application. It contains a quantity of active substance equivalent to 1% Diclofenac Sodium. Dicloran gel can be easily rubbed into the skin due to its unique gel base.
2. Dicloran gel has major anti-inflammatory properties, which apparently are related to the inhibition of cyclo-oxygenase, a decrease in prostaglandin synthesis, and an increase in the reuptake of arachidonic acid into cellular pools.
3. Dicloran gel is suitable for use in inflammatory and degenerative rheumatic disease, as well as for the treatment of post-traumatic inflammation and swelling.

Pharmacokinetics
Clinical Pharmacology:
Diclofenac is a Nonsteroidal anti-inflammatory drug (NSAID). In Pharmacologic studies, Diclofenac has shown anti-inflammatory, antipyretic and analgesic activity. As with the other NSAIDs, the mode of action is not known. Its ability to inhibit prostaglandin synthesis, may however be involved in its anti-inflammatory activity, as well as contribute to its efficacy in relieving pain related to inflammation and primary dysmenorrhea. With regards to its analgesic effect, diclofenac is not a narcotic.

Indications:
Local symptomatic relief of pain and inflammation in trauma of tendons, ligaments, muscles and joints; e.g. due to sprains, strains and bruises; localised forms of soft tissue rheumatism. Topical therapy of osteoarthritis of superficial joints and acute musculoskeletal disorders e.g. tenosynovitis, myositis, Bursitis.

Dosage and Administration:
Depending on the size of the painful site to be treated, apply 2-4g Dicloran Gel 3-4 times daily to the affected area and rub in gently.

Dosage
As a general recommendation, the dose should be individually adjusted. Adverse Effects may be minimized using the lowest effective dose for the shortest duration necessary to control symptoms (see section WARNINGS AND PRECAUTIONS).

Established cardiovascular disease or significant cardiovascular risk factors
Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≤100mg daily if treated for more than 4 weeks (See Section WARNING AND PRECAUTIONS).

Route of Administration:
Topical

Contraindications:
Dicloran gel is contraindicated in patients with a history of hypersensitivity to Diclofenac. Aspirin and other non-steroidal anti-inflammatory drugs
Severe cardiac failure (see Section WARNINGS AND PRECAUTIONS)

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

Warning:
Cardiovascular Effects
Treatment with NSAIDs including diclofenac, particularly at high dose and in long term, maybe associated with an increased risk of serious cardiovascular thrombotic events (including myocardial infraction and stroke).

168 mm

125 mm

Back

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As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest duration possible. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially when treatment continuous for more than 4 weeks.
Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. Chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.

Precautions:
1. Dicloran Gel should be applied only to intact skin surfaces and not to skin wounds or open injuries. It should not be allowed to come into contact with eyes or with mucous membranes.
2. Where Dicloran gel is applied to relatively large area of skin and over a prolonged period, the possibility of systemic side effects cannot be completely excluded.
3. Severe cutaneous reactions, including Stevens - Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs. Adverse effects: Dermatological: Occasional - rashes or skin eruptions Cases of hair loss, bullous eruptions, erythema multiforme, Stevens- Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.
4. Since no experience has been acquired with Dicloran Gel in pregnant women, it is not recommended for use during pregnancy.

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

Side Effects:
Dicloran gel is usually well tolerated. Itching, reddening or smarting on the skin or outbreak of a skin rash may occasionally occur.

Adverse Drug Reactions
Cardiac Disorders
Uncommon*: Myocardial infraction, cardiac failure, palpitations, chest pain. *The frequency reflects data from long-term treatment with a high dose (150mg/day).

Description of selected adverse drug reactions
Arteriothrombotic events
Meta-analysis and pharmacoepidemiological data point towards an increased risk of arteriothrombotic events (for example myocardial infraction) associated with the use of diclofenac, particularly at a high dose (150mg daily) and during long-term treatment (see section WARNINGS AND PRECAUTIONS).

Storage:
Store below 30°C. Do not freeze

Shelf Life:
3Years

Presentation:
Tube of 20g / 50g

Manufactured by:
UNIQUE PHARMACEUTICAL LABORATORIES
(A Division of J.B Chemicals & Pharmaceuticals Limited)
Plot No. 304-308, G.I.D.C, Industrial Area, Panoli, Bharuch, 394116, India
Product Registration Holder:
Unimed Sdn Bhd
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara 52200,
Kuala Lumpur, Malaysia.

Date of Revision: August 2024
*** Trade Mark**

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168 mm

125 mm

Pantone : Black

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Date: 10-10-2024, 25-10-2024