

**DORIVAN GEL**  
**(DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE,**  
**MENTHOL AND BENZYL ALCOHOL GEL)**



**1.3.1 Summary of Product Characteristics (smpc)**

**1. Name of the medicinal product**

**1.1 (Invented) name of the medicinal product**

DORIVAN GEL

**INN (GENERIC NAME)**

DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE, MENTHOL  
AND BENZYL ALCOHOL GEL

**1.2 Strength:- --**

**1.3 Pharmaceutical form:- Gel**

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## 2. COMPOSITION

**DORIVAN GEL**  
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Composition:

Diclofenac Diethylamine BP 1.16% w/w

Eq. To Diclofenac Sodium BP 1.0% w/w

Linseed Oil BP 3.0% w/w

Methyl Salicylate BP 10.0% w/w

Menthol USP 5.0% w/w

Benzyl Alcohol BP 1.0% w/w

(As Preservative)

Gel Base: qs

**2000 TUBES (30 g): 60 kg**

Sr. No.	Ingredients	Specification	mg/tube	Label Claim % w/w	Overages (%)	%w/w	Required Qty. (kg)
1	Diclofenac Diethylamine	BP	355	1.16	2.0	1.183	0.710
2	Linseed Oil	BP	900	3	-	3.00	1.8
3	Methyl Salicylate	BP	3060	10	2	10.2	6.12
4	Menthol	USP	1605	5	7	5.35	3.21
5	Cetostearyl Alcohol	BP	600	-	-	2	1.20
6	Cetomacrogol 1000	BP	600	-	-	2	1.20
7	Hydrogenated Caster Oil	BP	300	-	-	1	0.600
8	Carbomer-934 P	BP	360	-	-	1.2	0.72
9	Propylene Glycol	BP	900	-	-	3.0	1.800
10	Di sodium Edetate	BP	30	-	-	0.1	0.06
11	Polysorbate80	IHS	750	-	-	2.5	1.50
12	Benzyl Alcohol	BP	300	1.0		1.0	0.60
13	Triethanolamine	BP	180	-	-	0.6	0.360
14	Purified Water	BP	20060	-	-	q.s	40.120
	<b>Total Weight of the Batch</b>				<b>60 kg</b>		
	<b>Average Net Weight per Tube</b>				<b>30 gm</b>		

BP = British Pharmacopoeia

IH = In-House Specification

USP = United States Pharmacopeia

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### **3. PHARMACEUTICAL FORM. :**

**Description:** A smooth Transparent colourless Gel.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications:**

Gel is indicated in adults and adolescents aged 14 years and over as anti-inflammatory and analgesic agent in the treatment of:

- mild to moderate muscle pain;
- contusions;
- post-traumatic pain.

#### **4.2 Posology and method of administration:**

Posology

Adults and children over 14 years: apply the formulation on the skin 3-4 times in a day and rub in gently. The quantity of formulation to be used depends upon the size of the painful area. A single dose is 2-4 g (4-8 cm when the tube neck is fully open).

There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age.

The duration of treatment without consulting a physician should not exceed 7 days.

The possibility of a long-term use of medicine the doctor decides individually.

Method of administration

Cutaneous use.

Apply on healthy skin only.

After application, the hands should be washed, unless these are being treated.

Gel can be used as additional treatment to the oral administration of non-steroidal anti-inflammatory drugs.

#### **4.3 Contraindications:**

Hypersensitivity to the active substance or to any of the excipients used in the formulation.

- Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- The use in children and adolescents aged less than 14 years is contraindicated.
- Third trimester of pregnancy.
- Patients with renal impairment

#### **4.4 Special warnings and precautions for use:**

Gel should be applied only on unbroken skin and not on open wounds. Occlusive dressing is not recommended after application. Care should be taken to avoid contact with the eyes and mucous membranes.

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Use with caution in: severe disorders of the liver and kidney functions, bronchial asthma, pregnancy (first and second trimesters), elderly patients.

- Muscoleve contains Benzyl alcohol which may cause mild local irritation;
- Muscoleve contains Butylated Hydroxy Toluene and Butylated Hydroxy Anisole which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
- Muscoleve contains Polyoxyl 40 Hydrogenated Caster Oil which may cause skin reactions;
- Muscoleve contains propylene Glycol which may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large area of broken or damaged skin (such as burn) without talking to you doctor or pharmacist.

#### **4.5 Interaction with other medicinal products and other forms of interaction:**

Diuretics, Angiotensin Converting Enzyme Inhibitors (ACE inhibitors) and Angiotensin II Antagonists (AII): NSAIDs may decrease the effectiveness of diuretics and other antihypertensive medicinal products. In some patients with impaired renal function (e.g., dehydrated patients or elderly with impaired renal function) the co-administration of an ACEI or AIIA and cyclooxygenase inhibitor agents may result in the progression of renal function deterioration, including the possibility of acute renal insufficiency, which is usually reversible. The occurrence of these interactions should be considered in patients applying diclofenac particularly if in large areas of the skin and for prolonged periods, in combination with ACEI or AIIA. Consequently, this drug combination should be used with caution, especially in elderly patients. Patients should be properly hydrated and the need to monitor the renal function after the beginning of the concomitant therapy and periodically thereafter should be analysed. Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely.

#### **4.6 Pregnancy and lactation:**

##### **Pregnancy**

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. 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 topical diclofenac 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, this medicinal product 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 topical diclofenac has no or negligible influence on the ability to drive and use machines.

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#### **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 ( $\geq 1/100, < 1/10$ ); uncommon ( $\geq 1/1,000, < 1/100$ ); rare ( $\geq 1/10,000, < 1/1,000$ ); 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: Burning sensation at the application site

Dry skin

Although less likely with the topical administration, some side effects normally associated with systemically administered diclofenac may also occur.

The prolonged use of diclofenac in a relatively extensive area can cause systemic side effects such as nausea, vomiting, diarrhoea or epigastric pain.

#### **4.9 OVERDOSE:**

The low systemic absorption of topical diclofenac renders overdoses very unlikely.

However, undesirable effects similar to those observed following an overdose of Diclofenac tablets can be expected if Topical diclofenac is inadvertently ingested (1 tube of 100 g contains the equivalent of 1,000 mg diclofenac sodium).

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. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

### **5 Pharmacological Properties:**

#### **5.1 Pharmacodynamic properties:**

Pharmacotherapeutic group: Topical products for joint and muscular pain, Anti-inflammatory preparations, non-steroids for topical use, ATC code: M02AA15

Diclofenac is a phenylacetic acid derivative. It leads to the inhibition of cyclooxygenase activity, which then leads to the inhibition of the synthesis of prostaglandin and other mediators

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of inflammation. Diclofenac acts as anti-inflammatory and analgesic agent in the treatment of topical symptoms of rheumatic and non-rheumatic pains of the locomotor apparatus.

## **5.2 Pharmacokinetic properties:**

### **Absorption**

After topical application, diclofenac is well-absorbed into the subcutaneous layers of the skin. In healthy volunteers, the maximum level of diclofenac after a 7.5 g dose of 1% of concentration was, on average, approximately 3.9 ng/ml. After several days of treatment, the concentration on skin and soft tissues of patients with arthrosis reached values 30 to 40 times higher than the ones from plasma. The diclofenac absorption in the 1% concentration applied on the healthy skin reached 6 to 7% in healthy individuals.

### **Distribution**

The diclofenac concentration was measured on plasma and tissue and synovial fluid after topical administration in the hands and knees joints. Maximum plasma concentration was about 100 times lower than after oral administration. Diclofenac binds 99.7% to plasma proteins, mainly albumin (99.5%).

### **Biotransformation**

Biotransformation of diclofenac involves partly glucuronidation of the intact molecule, and mainly single and multiple hydroxylations, most of which are converted to glucuronide conjugates (hydroxyl-glucuronates). The main metabolite is 4-hydroxy-diclofenac (30%-40%). All the metabolites are biologically active, but to a much smaller extent than diclofenac.

### **Elimination**

Diclofenac and its metabolites are excreted mainly in the urine. Total clearance of diclofenac from plasma is  $263 \pm 56$  ml/min. The terminal plasma half-life is of 1-2 hours. Its metabolites have similar plasma half-lives of 1-3 hours. Approximately 60% of the dose administered is eliminated in the urine in the form of metabolites, only 1% in the form of diclofenac. The remaining is eliminated as metabolites by bile and in faeces.

## **5.3 Preclinical safety data:**

Not Applicable

## **6 Pharmaceutical Particulars**

### **6.1 List of Excipients.**

Cetostearyl Alcohol BP, Cetomacrogol 1000 BP, Hydrogenated Caster Oil BP, Carbomer-934 P BP, Propylene Glycol BP, Di sodium Edetate BP, Polysorbate80 IH, Triethanolamine BP, Purified Water BP.

### **6.2 Incompatibilities**

Not applicable.

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**6.3 Shelf life**

3 Years

**6.4 Special precautions for storage**

Store in cool & dry place. Do not freeze.

**6.5 Nature and contents of container**

30g laminated tube.

**7. Name of Applicant Manufacturer**

**Manufacturing country:** INDIA

**Manufacturer:** MEDICO REMEDIES LTD.

**Address of the Manufacturing plant:**

7, 8 & 9, Dewan & Sons Udyog Nagar,  
Palghar, - 401 404,  
Maharashtra. (INDIA)

**E-mail :** info@medicoremedies.com

medicoremedies@yahoo.com

**Tel. No. :** +912525 252868 / 256381

**WEBSITE:** www.medicoremediesindia.com