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

DICLOGESIC GEL

1. Generic Name

Diclofenac, Virgin Linseed Oil, Methyl Salicylate, Menthol & Capsaicin Gel

2. Qualitative and quantitative Composition:

Diclofenac Diethylamine I.P. ……. 1.16% w/w

(eq. to Diclofenac Sodium 1% w/w)

Virgin Linseed Oil B.P. ……. 3% w/w

(Containing Predominantly

Alpha Linolenic Acid)

Methyl Salicylate I.P. ……. 10% w/w

Menthol I.P. ……. 5% w/w

Capsaicin U.S.P. ……. 0.025% w/w

Preservative:

Benzyl Alcohol I.P. …… 1% w/w

Gel Base ……. q.s.

The list of excipients used are Benzyl Alcohol, Stearic Acid, Glyceryl Monostearate, Propylene Glycol, Triethanolamine, Carbomer, Methyl Paraben, Propyl Paraben and Butylated Hydroxy Toluene.

3. Dosage form and strength

Dosage form: Gel

Strength: 1.16% w/w + 3% w/w + 10% w/w+ 5% w/w + 0.025% w/w

4. Clinical particulars

4.1. Therapeutic indication

Treatment of:

- Localized forms of soft-tissue rheumatism, e.g. tenovaginitis, shoulder-hand syndrome, bursitis and peri arthropathy.
- Localized rheumatic diseases, e.g., osteoarthritis of the peripheral joints and vertebral column.
- Post –traumatic inflammation of the tendons, ligaments, muscles, and joints e.g., due to sprains, strains, or bruises.

4.2. Posology and method of administration

Diclogesic Gel is applied locally 3-4 times daily to the skin and rubbed in gently. Depending on the size of the painful area to be treated, 2-4 g Diclogesic Gel is sufficient to treat an area of about 400-800 cm2. An occlusive dressing should not be used. The hands should be washed after application of the gel, unless the hands are the treated areas, in which case, they should be washed 30 minutes after application. Heating pads should not be used with Diclogesic Gel, and patients should avoid taking a hot bath or shower immediately before or after application

as the burning sensation may be exacerbated. The duration of treatment should not be longer than one week (7 days).

For external use only

4.3. Contraindications

- Hypersensitivity to diclofenac, acetylsalicylic acid, and other non-steroidal anti-inflammatory agents, to capsaicin, menthol, benzyl alcohol and to isopropanol or propylene glycol.

4.4. Special warnings and precautions for use

Precautions

Diclogesic Gel should be applied only to intact skin, and not be broken or irritated skin or open wounds. The preparation should not come into contact with the eyes or mucous membranes. It should be used with care on the extremities of patients with impaired peripheral circulation or diabetes. The gel should not be used before phototherapy or phototesting procedures.

4.5. Drugs interactions

No interactions have been reported to date with topical diclofenac diethylamine. Potentiation of warfarin anticoagulation has been reported with topical application of methyl salicylate preparations.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Use in pregnancy.

For Diclogesic Gel no clinical data on exposed pregnancies are available. Animal studies are insufficient with respect to effects on pregnancy/and - or /embryonal / foetal development /and-or /parturition/and-or /postnatal development. The potential risk for humans is unknown.

Diclogesic Gel should not be used during pregnancy unless clearly necessary.

Use during lactation.

Measurable quantities of the active substance should not be seen in the breast milk. However, no experience is available with Diclogesic Gel in breast-feeding women.

Children

Diclogesic Gel should not be used in children.

4.7. Effects on ability to drive and use machines.

Diclogesic gel has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Local reactions

Very common: a warm, stinging, or burning sensation may be experienced at the site of application. Allergic or nonallergic nonallergic contact dermatitis (with symptoms and signs such as itching, reddening of the skin or scaling).

Common: Moderate allergic and non-allergic contact dermatitis such as erythema, oedema, papules, vesicles, and bullae.

Systemic reactions

Isolated cases: generalized rash; hypersensitivity reactions (e.g. asthma attack, angioedema); photosensitivity reactions.

Although likelihood of systemic reactions occurring during topical treatment with diclofenac is small compared with the frequency of side effects seen during oral administration, the possibility of developing other diclofenac adverse reactions cannot be completed ruled out. Since methyl salicylate is absorbed through the skin, symptoms of salicylate intoxication can occur following topical application of methyl salicylate.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com or at email: pv@torrentpharma.com or call on 1800-120-3001.

4.9. Overdose

Significant systemic reactions resulting from improper use or accidental over dosage should be treated with the usual measure employed to manage poisoning with non-steroidal anti-inflammatory drugs.

5. Pharmacological properties

5.1. Mechanism of Action

Diclofenac works by blocking the effect of chemicals called cyclo-oxygenase (COX) enzymes. These enzymes help to make other chemicals in the body, called prostaglandins. Some prostaglandins are produced at sites of injury or damage causing pain and inflammation. By blocking the effect of COX enzymes, fewer prostaglandins are produced, which means pain and inflammation are eased. The linseed oil helps in the penetration of the diclofenac through the skin. Methyl salicylate also acts as an analgesic and menthol gives relief due to its cooling effect.

5.2. Pharmacodynamic properties

Diclogesic Gel is an analgesic, anti-inflammatory preparation for topical application. Its active substances include Oleum-lini, diclofenac diethylamine, capsaicin, methyl salicylate and menthol. The gel is applied to the skin. The properties of the combination of all four active ingredients in Diclogesic Gel have not been evaluated directly in clinical efficacy studies.

Oleum lini - contains predominantly essential fatty acids i.e. a - linolenic acid. When it is absorbed percutaneously, alpha - linolenic acid gets converted to eicosapentaenoic acid (EPA). EPA is acted upon by cyclo-oxygenase enzyme to produce prostaglandin E3 which is a weak inflammatory agent. Presence of EPA prevents the action of cyclooxygenase on Arachidonic acid which reduces its conversion to PGE2 (a highly inflammatory agent).

Diclofenac has been shown in experiments to inhibit prostaglandin biosynthesis; and this is regarded as an important factor in its mechanism of action.

Capsaicin gels and creams (in concentrations ranging from 0.025% - 0.075%) have been used as topical analgesics in painful conditions such as post-herpetic neuralgia after the lesions have healed, diabetic neuropathy, osteoarthritis, and rheumatoid arthritis. The mechanism of analgesic effect of capsaicin is believed to result from stimulation of the release of substance P from local sensory C-type nerve fibers and subsequent depletion of substance P from the entire neuron, reducing the transmission of pain impulses to the CNS. Capsaicin is not considered to be a traditional counterirritant, because it does not rely on vasodilation in the skin for its mechanism of action, but it has been included in various rubefacient preparations for the relieve of muscular and rheumatic pain. Local application may result in a transient warm, burning, or stinging sensation corresponding to transient excitation of the pain fibres, followed by hypoalgesia due to inactivation of the pain fibres.

Methyl salicylate is a salicylic acid derivative that is irritant to the skin and is used topically as a counterirritant in rubefacient preparations for the relief of pain in musculoskeletal, joint and soft tissue disorders. Like other salicylates, methyl salicylate may be absorbed through intact skin. A

study evaluating other commercial formulations containing 20% methyl salicylate indicated that the methyl salicylate is extensively metabolized to salicylic acid in the dermal and subcutaneous tissues following topical administration.

Menthol is a common counterirritant in various topical analgesic preparations. When applied to the skin, menthol dilates the blood vessels, causing a sensation of coldness followed by an analgesic effect.

5.3. Pharmacokinetic properties

Absorption

Diclofenac

The amount of diclofenac absorbed through the skin is proportional to the contact time and skin area covered with Diclofenac sodium gel and depends on the total topical dose and on skin hydration. About 6% of the active substances is absorbed after topical application of 2.5 g Diclofenac sodium gel per 500 cm2, as determined by reference to total renal elimination compared with diclofenac sodium tablets. Absorption of diclofenac increases threefold if an occlusive dressing is applied for 10 hours.

Capsaicin

The absorption of capsaicin after topical application is unknown.

Methyl salicylate

Methyl salicylate is speedily absorbed when applied cutaneously. Percutaneous absorption of methyl salicylate is enhanced by exercise, heat occlusion, or disruption of integrity of the skin.

Both the rate and extent of absorption increase after repeated application.

Menthol

Menthol is known to be well absorbed after topical application.

Distribution

Diclofenac

Diclofenac can be detected in plasma, synovial tissue, and synovial fluid after topical application of diclofenac sodium gel to the wrists and knees. Peak plasma concentrations of diclofenac are about 100 times lower after topical application of diclofenac sodium gel than after oral administration of diclofenac sodium tablets. 99.7% of diclofenac binds to serum proteins, mainly to albumin (99.4%).

Capsaicin

The distribution of capsaicin after topical application is unknown.

Methyl salicylate

50-80% of salicylic acid binds to serum proteins.

Menthol

The distribution of menthol after topical application is unknown.

Metabolism

Diclofenac

Biotransformation of diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single or multiple hydroxylation resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a much lesser extent than diclofenac.

Capsaicin

Capsaicin seems to be metabolized by cytochrome P450

Methyl salicylate

Methyl salicylate is extensively metabolized to salicylic acid in the dermal and subcutaneous tissues following topical administration.

Menthol

The metabolism of menthol after topical application is unknown.

Elimination

Diclofenac

Total systemic clearance of diclofenac from the plasma is 263 ± 56 mL/min (mean value ± standard deviation). The terminal plasma half-life is 1-2 hours. Four of the metabolites, including the two active metabolites, also have a short plasma half-life (1-3 hours). One metabolite, 3'-hydroxyl-4-methoxy-diclofenac, has a much longer half-life, but the metabolite is virtually inactive. Diclofenac and its metabolites are excreted mainly in the urine.

Capsaicin

The elimination of capsaicin after topical application is unknown.

Methyl salicylate

Salicylic acid and its principal metabolites are excreted in the urine.

Menthol

After absorption, menthol is excreted in the urine and bile as a glucuronide.

Kinetics in special clinical situations

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

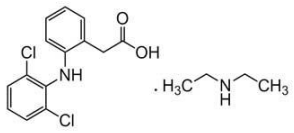
6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Not applicable

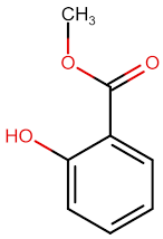
7. Description

Diclofenac Diethylamine is diethylammonium 2-[(2,6-dichloroanilino)phenyl]acetate. The empirical formula is $C_{18}H_{22}Cl_2N_2O_2$, and its molecular weight is 369.3 g/mol. The chemical structure of Diclofenac Diethylamine is:

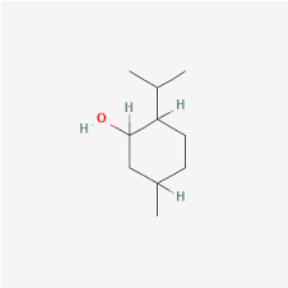


Virgin Linseed Oil is Linseed oil is a rich source of α-Linolenic acid extracted from the dried, ripened seeds of the flax plant Linum usitatissimum. It is use to reduces inflammation and improves blood circulation at the site of application.

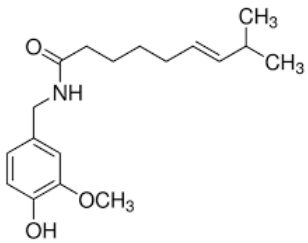
Methyl Salicylate is 2-hydroxybenzoic acid methyl ester. The empirical formula is $C_8H_8O_3$ and its molecular weight is 152.2 g/mol. The chemical structure of Methyl Salicylate:



Menthol is 5-methyl-2-(1-methylethyl). The empirical formula is $C_{10}H_{20}O$ and its molecular weight is 156.3 g/mol. The chemical structure of Menthol:



Capsaicin is (E)-N-[(4-hydroxy-3-methoxyphenyl)methyl]-8-methylnon-6-enamide. The empirical formula is $C_{18}H_{27}NO_3$and its molecular weight is 305.4 g/mol. The chemical structure of Capsaicin:



Diclogesic Gel

Diclofenac, Virgin Linseed Oil, Methyl Salicylate, Menthol & Capsaicin Gel is an off white semi solid mass with characteristic odour.

The list of excipients used are Benzyl Alcohol, Stearic Acid, Glyceryl Monostearate, Propylene Glycol, Triethanolamine, Carbomer, Methyl Paraben, Propyl Paraben and Butylated Hydroxy Toluene.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than the date of expiry.

8.3. Packaging information

Diclogesic Gel is available in Tube of 10 gm, 30 gm, 50 gm and 75 gm

8.4. Storage and handing instructions

Store at temperature below 30ºC. Do not Freeze.

Keep all medicines out of reach of children.

Keep the tube tightly closed after use.

Warning: Not for veterinary use.

Avoid contact with eyes, mouth & other mucous membranes.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies.
- Have kidney or liver problems.
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have any serious illness.
- Are taking any medicines (prescription, over the counter, vitamins, or herbal products)

10. Details of manufacturer

Akums Drugs & Pharmaceuticals Ltd.

At: Plot No.26A, 27-30,

Sector -8A, I.I.E.,

SIDCUL, Ranipur, Haridwar-249403,

Uttarakhand.

11. Details of permission or licence number with date

Mfg. Lic. No. is 4/UA//LL/2014, issue on 12.03.2021.

12. Date of revision

MAY-2026

MARKETED BY

TORRENT PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/DICLOGESIC GEL/MAY 2026 /02/PI