

Epidic[®] gel

(Diclofenac Diethylamine, Linseed Oil, Menthol & Methyl Salicylate Gel)

Composition:

Diclofenac Diethylamine IP.....	1.16% w/w
Linseed Oil BP.....	3.00% w/w
Methyl Salicylate IP... ..	10.00% w/w
Menthol IP.....	5.00% w/w
Benzyl Alcohol (Preservative) IP.....	1.00% w/w
Gel base... ..	q.s.

Clinical Pharmacology:

Diclofenac Diethylamine: It is a strong Non Steroidal anti inflammatory Drug. The mechanism of action of diclofenac is similar to that of other NSAIDs. Diclofenac inhibits the enzyme, COX, an early component of the arachidonic acid cascade, resulting in the reduced formation of prostaglandins, thromboxanes and prostacyclin.

Linseed Oil:

Linseed oil, also known as flaxseed oil or flax oil it is a colourless to yellowish oil obtained from the dried, ripened seeds of the flax plant (*Linum usitatissimum*). It has rich source of Omega 3, Omega 6 and omega 9 fatty acids. Due to abundant source of Omega 3 fatty acids it produces anti inflammatory effects.

Methyl salicylate:

It is a salicylic acid derivative. Salicylates inhibit cyclooxygenase, thereby reducing the formation of prostaglandins, and cause platelet dysfunction. Methyl salicylate is used topically as a counter-irritant. Upon application, it is absorbed through the skin and is applied for the relief of pain in rheumatic conditions and painful muscle or joints.

Menthol:

It 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 drugs when applied on the skin, to give a faster onset of action.

Indications:

Indicated for the treatment of pain, swelling and inflammation due to musculo-skeletal disorders (such as sprains, strains, tendonitis, bursitis, hand, neck, shoulder pain, sciatica, muscle stiffness, joint pain and backache).

Contraindications:

- The use of Epidic Gel is contraindicated in patients with a known hypersensitivity to diclofenac and/or any other active ingredient or excipient.
- Epidic Gel should not be administered in patients who have experienced asthma, urticaria, or other allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) or salicylate idiosyncrasy. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.
- Epidic Gel is contraindicated in the setting of Coronary Artery Bypass Grafting (CABG) surgery.
- Epidic Gel is contra-indicated on broken or irritated skin.

Eye Exposure:

Contact of diclofenac gel with eyes and mucosa, although not studied, should be avoided. Patients should be advised that if eye contact occurs, they should immediately wash out the eye with water or saline and consult a physician if irritation persists for more than an hour.

Diclofenac gel should not be applied to open wounds.

Route of administration: Topical.

FOR EXTERNAL USE ONLY

Dosage:

Apply gently over affected area twice daily or as directed by the Physician.

Storage:

Keep out of reach of children.

Keep the tube tightly closed after use.

Keep in cool and dry place.

Do not freeze.

Presentation: Epidic gel available as 30 gm tube.

Marketed By:



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