

Diclofenac Gel BP

POM

COMPOSITION:

Diclofenac Diethylamine BP	1.16% w/w
Eq. to Diclofenac Sodium	1.00% w/w
Gel base	Q.S.

PHARMACOLOGICAL CLASS:

Non-steroidal Anti-inflammatory and Analgesic

PHARMACOLOGICAL ACTION:

Diclofenac is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Diclofenac is a potent non-steroidal anti-inflammatory drug with analgesic and antipyretic properties. It also has some uricosuric effect. Diclofenac inhibits cyclo-oxygenase activity with a reduction of production of prostaglandins in the tissue.

Pharmacokinetic:

When Diclofenac Gel is applied locally, the active substances are absorbed through the skin, determined by reference to the urinary excretion of Diclofenac and its hydroxylated metabolites. After topical administration of Diclofenac Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid.

INDICATIONS:

Diclofenac Gel is used to relieve pain and reduce swelling in a number of painful conditions affecting the joints and muscles. It relieves rheumatic and muscular pain, and reduces swelling and inflammation, e.g., in injuries involving the tendons, ligaments, muscles and joints. For the relief of sprains, strains or bruises, backache, tendinitis (e.g., tennis elbow), and for localized and mild arthritis.

CONTRAINDICATIONS:

Hypersensitivity to Diclofenac, acetylsalicylic acid, isopropanol propylene glycol or other components of the gel base.

Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents (NSAIDs).

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

SPECIAL PRECAUTIONS AND WARNINGS:

Diclofenac Gel should be applied only to intact skin and or open wounds. It should not come into contact with the eyes or mucous membranes.

Pregnancy : Since no experience has been acquired with Diclofenac Gel in pregnancy or lactation, it is not recommended for use in these circumstances.

During the last trimester of pregnancy the use of prostaglandin synthetase inhibitors may

result in premature closure of the ductus arteriosus, or in uterine inertia.
Animal data has shown an increased incidence of dystonia and delayed parturition when drug administration is continued into late pregnancy.

Lactation: It is not known whether topical diclofenac is excreted in human milk, and Diclofenac Gel is therefore not recommended during breast-feeding, if there are compelling reasons for using Diclofenac Gel during breast feeding it should not be applied to the breast or to large areas of skin, nor should it be used for a prolonged period.

ADVERSE EFFECTS:

Occasional skin rash, itching and redness of the skin.

DOSAGE AND DIRECTIONS FOR USE:

Adults and Adolescents over 12 years of age: Depending on the size of the painful area to be treated, 2-4 g (a circular shaped mass approximately 2.0-2.5cm in diameter) Diclofenac Gel should be applied 3-4 times daily to the affected sites and gently rubbed-in.

Duration of treatment depend on the indication and the patient's response. It is advisable to review the treatment after 2 weeks.

OVERDOSAGE:

There has been no experience of overdose with Diclofenac gel.

DRUG INTERACTIONS:

Systemic absorption of Diclofenac Gel is low and hence the risks of interactions are less. No drugs interactions have been reported with Diclofenac Gel to date.

PRESENTATION:

Tube pack

STORAGE INSTRUCTIONS:

Store below 30°C. Protect from light.

DATE OF PUBLICATION:

01.07.2014

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E-P0714