SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME

GENERIC: DICLOFENAC GEL BP 1% w/w

BRAND NAME: DINAC GEL

DESCRIPTION:

Clear Transparent Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Diclofenac Diethylamine BP 1.16 % w/w

equivalent to Diclofenac Sodium BP…….1 % w/w

In a gel base……q.s.

3. PHARMACEUTICAL FORM:

Topical semi-solid dosage form - Gel

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

Dinac Gel is used to treat pain and reduces swelling caused by a variety of local conditions, usually affecting the joints, ligaments, tendons and muscles. These include, Sprains, soft tissue injuries, rheumatism of soft tissues and mild arthritis, such as in the knee or hand.

4.2 Posology and method of administration

Dinac Gel should be thinly applied 3-4 times daily to affected areas and rubbed gently

OR

As directed by physician

4.3 Contraindications

Do not use gel in children below 12 years of age.

4.4 Warning and precautions for use

The possibility of systemic adverse events from application of Dinac Gel cannot be excluded if the preparation is used on large areas of skin and over a prolonged period.

Dinac Gel contains propylene glycol, which may cause mild, localized skin irritation in some people.

Concomitant use of oral NSAID's should be cautioned as the incidence of untoward effects, particularly systemic side effects, may increase.

Dinac Gel should not be co-administered with other products containing diclofenac.

Dinac Gel should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should not be ingested.

Discontinue the treatment if a skin rash develops after applying the product.

Dinac Gel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Some possibility of gastro-intestinal bleeding in those with a significant history of this condition has been reported in isolated cases.

4.5 Drug Interactions

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

4.6 Pregnancy & Lactation

Use in Pregnancy

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;
The mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.
Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Use in Lactation
Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Dinac Gel 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, Dinac Gel 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:
Not applicable.

4.8 Adverse Effects
Itching, smarting, reddening, or blistering of skin where the gel has been applied such effects are often mild and should wear off after few days. If they are severe, or last more than a few days ,consult doctor or pharmacist.

4.9 Overdose
Signs and symptoms
The low systemic absorption of Dinac Gel renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if Dinac Gel is inadvertently ingested (1 tube of 100g contains the equivalent of 1000mg of 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

Treatment

Management of overdosage with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from Dinac Gel overdosage. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

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 M02A A15).

Diclofenac, the active component of Dinac Gel has anti-inflammatory, anti-nociception, and antipyretic effects.

The mechanism of action of diclofenac is similar to that of other nonsteroidal anti-inflammatory drugs. Diclofenac inhibits the enzyme, cyclooxygenase (COX), an early component of the arachidonic acid cascade, resulting in the reduced formation of prostaglandins, thromboxanes and prostacylin. It is not completely understood how reduced synthesis of these compounds results in therapeutic efficacy.

5.2 Pharmacokinetic properties

When Dinac Gel is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Dinac Gel.

After topical administration of Dinac Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of Dinac Gel.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer-940,Propylene glycol, Butylated hydroxytoluene, Disodium Edetate, Diethylamine, Isopropyl alcohol

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 Months

6.4 Special precautions for storage:

Store in a cool place below 25°C.

6.5 Nature and contents of container

20 g Collapsible aluminium tube in a carton along with insert.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements

7. APPLICANT

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

8. WHO PREQUALIFICATION REFERENCE NUMBER

Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION

Not applicable

10. DATE OF REVISION OF THE TEXT

Not applicable