SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME

GENERIC: DICLOFENAC GEL BP 1% w/w

BRAND NAME: VITE GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diclofenac Diethylamine BP 1.16 % w/w

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

In a gel base……q.s.

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

Topical semi-solid dosage form - Gel

Clear Transparent Gel

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

Vite Gel is indicated for the relief of the pain and reduces swelling caused by a variety of local conditions, usually affecting the joints, ligaments, tendons and muscles, amenable to topical treatment, such as the knees and those of the hands. 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

Vite Gel should be thinly applied 2-3 times daily to affected areas and rubbed gently OR

As directed by physician

4.3 Contraindications

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

4.4 Warning and precautions for use

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

Vite 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.

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

Vite 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.

Vite 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 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and 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 Vite 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, Vite 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:

Cutaneous application of Vite Gel has no influence on the ability to drive and use machines.

4.8 Adverse Effects

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common (> 1/10); common ≥(1/100, <1/10); uncommon ≥(1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (<1/10,000), not known: cannot be estimated from the available data.

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

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

Reporting of suspected 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.

4.9 Overdose

Signs and symptoms

The low systemic absorption of Vite Gel renders overdose very unlikely. However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if Vite 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 Vite 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).

Vite gel is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Due to an aqueous-alcoholic base the gel exerts a soothing and cooling effect.

5.2 Pharmacokinetic properties

When Vite 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 Vite Gel.

After topical administration of Vite 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 Vite Gel.

5.3 Preclinical safety data

None known.

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:

Do not store above 30°C. Protect from light, Do not freeze.

Vite Gel should be kept out of reach and sight of children.

6.5 Nature and contents of container

30 g Collapsible aluminium tube.

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

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8. FDA APPLICATION NUMBER (S)

NA

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

31-October-2017 RENEWAL DATE

10. DATE OF REVISION OF THE TEXT

Not applicable

Manufactured by:

S Kant HEALTHCARE Ltd.

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

Vapi - 396 195. Gujarat, INDIA.