DOSANAC®
DICLOFENAC EMULSION GEL

NAME AND STRENGTH OF ACTIVE SUBSTANCE
Each 1 g contains 11.6 mg diclofenac diethylammonium, which corresponds to 10 mg diclofenac sodium (Co-solvent: 5%w/w isopropyl alcohol)

PRODUCT DESCRIPTION
White to creamy white cream like gel

PHARMACODYNAMICS
Mechanism of action
Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with effective analgesic, anti-inflammatory and antipyretic properties. Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).
Diclofenac gel 1% is an anti-inflammatory and analgesic preparation designed for topical application. In inflammation and pain of traumatic or rheumatic origin, diclofenac gel 1% relieves pain and decreases swelling.

PHARMACOKINETICS
Absorption
The quantity of diclofenac absorbed through the skin is proportional to the size of the treated area, and depends on both the total dose applied as well as the degree of skin hydration.
Absorption amounts to about 6% of the applied dose of diclofenac after topical application of 2.5 g diclofenac gel 1% on 500 cm^2 skin, determined by total renal elimination, compared with diclofenac tablets. A 10-hour occlusion leads to a three-fold increase in the amount of diclofenac absorbed.
Distribution
Diclofenac concentrations have been measured from plasma, synovial tissue and synovial fluid after topical administration of diclofenac gel to hand and knee joints. Maximum plasma concentrations are approximately 100 times lower than after oral administration of the same quantity of diclofenac. 99.7% of diclofenac is bound to serums, mainly albumin (99.4%).
Diclofenac accumulates in the skin which acts as reservoir from where there is a sustained release of drug into underlying tissues. From the skin and underlying tissue, diclofenac preferentially distributes and persists in deep inflamed tissues (such as the joint), rather than in the bloodstream. Diclofenac is found in tissues at concentrations up to 20 times higher than in plasma.
Metabolism
The biotransformation of diclofenac involves single and multiple hydroxylation steps followed by glucuronidation, and glucuronidation of the intact molecule.
Elimination
The total systemic clearance of diclofenac from plasma is 263 ± 56 mL/min. The terminal plasma half-life is 1-2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1-3 hours. One metabolite, 3'-hydroxy-4'-methoxy-diclofenac, has a longer half-life but is virtually inactive. Diclofenac and its metabolites are excreted mainly in urine.
Renal and hepatic impairment
No accumulation of diclofenac and its metabolites is to be expected in patients suffering from renal impairment. In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of diclofenac are the same as in patients without liver disease.

INDICATIONS
For the external treatment of pain, inflammation and swelling in:
- injuries of the tendons, ligaments, muscles and joints (e.g. sprains, bruises, strains and back pain after sport or accidents);
- localized forms of soft tissue rheumatism such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, periarthropathies;
- and for the symptomatic treatment of osteoarthritis of small and medium-sized joints located close to the skin such as the finger joints or knee joints.

DOSAGE AND ADMINISTRATION
For cutaneous use only.
Adults and adolescents (aged 12 years and over)
Depending on the size of the painful area to be treated, 2-4 g of Dosanac Emulsion Gel (cherry to walnut size, sufficient to treat an area of about 400-800 cm^2) are applied 3 to 4 times daily to the affected areas and rubbed easily. The duration of treatment depends on the indication and the treatment success. It is advisable to check the treatment after 2 weeks should the symptoms have not improved.
Dosanac Emulsion Gel should not be used longer than 14 days. After application, the hands should be washed properly (except for treatment of finger arthritis). Dosanac Emulsion Gel can also be used as an adjunctive therapy with other diclofenac product.
Children or adolescents (under 12 years of age)
The use and safety of Dosanac Emulsion Gel in children under 12 years has not been tested systematically and is not recommended.

CONTRAINDICATIONS
- Known hypersensitivity to diclofenac or any of the excipients
- Patients in whom asthma, angioedema, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs)
- During the last trimester of pregnancy

WARNINGS AND PRECAUTIONS
Special warnings and precautions for use
The possibility of experiencing systemic adverse events (those associated with the use of systemic forms of diclofenac) should be considered if topical diclofenac is used at the higher dosage or for a longer period of time than recommended (see *Dosage and Administration*). Topical diclofenac should be applied only to intact, non-diseased skin, and not to skin wounds or open injuries. It should not be

Actual Size 100 %

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allowed to come into contact with the eyes or mucous membrane, and should not be ingested.
Discontinue the treatment if a skin rash develops after applying the product. Topical diclofenac can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.
Information concerning excipients
Diclofenac gel 1% contains propylene glycol and benzyl alcohol, which may cause mild, localized skin irritation in some people.
This preparation contains sodium metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.

INTERACTIONS
Since systemic absorption of diclofenac from a topical application is very low such interactions are very unlikely.

PREGNANCY AND LACTATION
Pregnancy
The use of diclofenac in pregnant women has not been studied, therefore, Dosanac Emulsion Gel should not be used during pregnancy. Dosanac Emulsion Gel is contraindicated during the third trimester of pregnancy, owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus.
Animal studies have not shown any direct or indirect harmful effects on pregnancy, embryonal/fetal development, parturition or postnatal development.
Lactation
It is not known whether topical diclofenac is excreted in breast milk, therefore, Dosanac Emulsion Gel is not recommended during lactation. If there are compelling reasons for using it, it should not be applied on the breasts or to large areas of skin, nor should it be used for a prolonged period.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
Cutaneous application of diclofenac gel has no influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS
Summary of Safety Profile
The adverse reactions tabulated below are classified according to frequency and system organ.

System Organ	Frequency	Adverse Reactions
Infection and Infestations	Very rare	: Rash pustular
Immune system disorders	Very rare	: Hypersensitivity (including urticaria), angioedema
Respiratory, thoracic and mediastinal disorders	Very rare	: Asthma
Skin and subcutaneous tissue disorders	Common	: Dermatitis (including contact dermatitis), eczema, rash, erythema, pruritus
	Rare	: Dermatitis bullous
	Very rare	: Photosensitivity reaction

OVERDOSE AND TREATMENT
The low systemic absorption of topical diclofenac renders overdose very unlikely.
However, undesirable effects, similar to those observed following an overdose of diclofenac tablets, can be expected if Dosanac Emulsion Gel is inadvertently ingested (1 unit of 100 g contains the equivalent of 1 g 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.

STORAGE CONDITIONS
Store below 30^{O}C
Protect from light and heat

SHELF LIFE
Refer to unit box for shelf-life.

DOSAGE FORMS AND PACKAGING AVAILABLE
Available in 25 g per aluminium tube

DATE OF REVISION OF PI
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Manufacturer :- SIAM BHEASACH CO., LTD.
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Product Registration Holder, Importer :- SPG PHARMA (MALAYSIA) SDN. BHD.
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