Diclogesic® 1% Gel

(Diclofenac Diethylamine)

Description: White to off-white opaque gel

Pharmacodynamics:
Diclogesic® gel is an anti-inflammatory and analgesic preparation for topical application. Its active substance corresponds to 1% diclofenac sodium. The white, creamy, non-greasy preparation is easy to rub into the skin, and its aqueous-alcohol base gives it a soothing and cooling effect. Diclofenac has been shown in experiment to inhibit prostaglandin biosynthesis and this is regarded as an important factor in its mechanism of action. In inflammation of traumatic origin, **Diclogesic®** gel has been shown to relieve pain, reduce oedema, and shorten the time to return of normal function.

Pharmacokinetics:
Absorption: The amount of diclofenac absorbed through the skin is proportional to the contact time and skin area covered with **Diclogesic®** gel, and depends on the total topical dose and on skin hydration. About 6 % of the active substance is absorbed after topical application of 2.5 g diclofenac gel per 500 cm2, as determined by reference to total renal elimination compared with diclofenac tablets. Absorption of diclofenac increases threefold if an occlusive dressing is applied for 10 hours.
Distribution: Diclofenac can be detected in the plasma, synovial tissue, and synovial fluid after topical application of diclofenac gel to the wrists and knees. Peak plasma concentration of diclofenac gel are about 100 times lower after topical application of diclofenac gel than after oral administration of diclofenac tablets. 99.7% of diclofenac binds to serum proteins, mainly to albumin (99.4%).
Metabolism: Biotransformation of diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single or multiple hydroxylation resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a much lesser extent than diclofenac.
Elimination: Total systemic clearance of diclofenac from the plasma is 263 ± 56 ml/min (mean value ± standard deviation). The terminal plasma half-life is 1-2 hours. Four of the metabolites, including the two active metabolites, also have a short plasma half-life (1-3hours). One metabolite, 3-hydroxy-4-methoxy-diclofenac, has a much longer half-life, but this metabolite is virtually inactive. Diclofenac and its metabolites are excreted mainly in the urine.
Kinetics in special clinical situations: No accumulation of diclofenac and its metabolites should occur in patients with renal insufficiency. In patients with chronic hepatitis or non-decompensate liver cirrhosis, the kinetics and metabolism of diclofenac are the same as in patients without liver disease.

Indication:
Diclogesic® gel is indicated in the local treatment of:
- Acute musculoskeletal disorders and back pain
- Traumatic inflammation of tendons, ligaments, muscles, and joints, due to pains, strains and bruises.
- Non-articular rheumatism
- Rheumatoid arthritis, osteoarthritis.

Dosage and administration:
Apply the gel to the painful site. Rub until it has fully penetrated the skin. Repeat this 3-4 times daily. The amount to be used depends on the site to be treated. The gel can be co -administered with other forms of **Diclogesic®** . Not to be used with occlusive dressings.

Contraindications:
Hypersensitivity to diclofenac, photosensitivity, acetylsalicylic acid and other non -steroidal anti -inflammatory drugs, as well as to isopropanol or propylene glycol. Contraindicated in children under 2 years of age.

Warnings and Precautions:
Diclogesic® gel should be applied to intact skin surfaces only. It should not be applied to neither open wounds or injures, nor to the eye or any mucous membrane. On prolonged use, some systemic side effects may arise such as gastrointestinal disturbances.
- Avoid usage when pregnant or breast feeding.
- Not suitable for children. May cause convulsion.
- Severe cutaneous reaction including Steven -Johnson Syndrome and toxic epidermal necrolysis (Lyell's syndrome) have been reported with diclofenac sodium.
- Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reaction.
- Discontinue diclofenac sodium immediately if rash occurs
- Can cause convulsion
- Contraindicated in children below 2 years of age
- Caution should be exercised when older children are treated
- Avoid direct application into the nostrils

THIS IS A MEDICAMENT
• Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
• Follow strictly the doctor's prescription, method of use and the instructions of pharmacist who sold the medicament
• The doctor and the pharmacist are experts in medicine, its benefits and risks
• Do not by yourself interrupt the period of treatment prescribed for you
• Do not repeat the same prescription without consulting your doctor

Interactions with other medicaments:
Avoid concomitant administration of two or more NSAID

Statement on usage during pregnancy and lactation:
Not applicable

Adverse effects/ Side effects:
Diclogesic® is well tolerated, however rarely skin- rash, itching, reddening and smarting of skin has been observed. Cases of hair loss, bullous eruptions, erthema multiforme, Steven-Johnson Syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Overdosage and Treatment:
In the event of significant systemic side - effects occurring as a result of improper use or accidental overdosage (eg. in children) general therapeutic measures of the kind normally adopted in order to treat poisoning with non -steroidal anti -inflammatory drugs should be restored to such as absorption should be prevented as soon as possible after the overdosage, supportive and symptomatic treatment should be given for complications such as hypertension, renal failure, convulsions, gastrointestinal irritation and respiratory depression.

Storage conditions:
Store in a dry place below 25 °C.
Keep medicament out of reach of children.
Jauhi daripada kanak- kanak.

Dosage forms and packaging available:
Diclogesic® Gel tube of 30 grains. Each gram contains 1% (w/w) Diclofenac sodium (as diclofenac diethylamine) in an emulsion gel.

Shelf-life: 3 years

Manufactured by: Dar Al Dawa Development & Investment Co., Ltd. P.O. Box 9364, Amman,11191, Jordan.

Date of Revision of package insert: 10/03/2022

Product Registration Holder and Distributor:

Antah Pharma Sdn. Bhd. No. 3, Jalan 1/19, 46300 Petaling Jaya,Selangor, Malaysia.

03/2022

Dar Aldawa

Diclogesic® 1% Gel

Color
Pantone Black U
Size: 205X135 mm
Item Code:
Pharma Code: