

Voren® Gel 1%

(Diclofenac Diethylamine B.P.)

ورین جیل ۱٪
(ڈیکلوفینک ڈائی ایٹھائل امائن بی پی)

COMPOSITION

Each gram of **Voren Gel** contains 11.6mg of diclofenac diethylamine equivalent to diclofenac sodium 10mg.

MECHANISM OF ACTION

Diclofenac is a phenylacetic acid derivative. It leads to the inhibition of cyclooxygenase activity, which then leads to the inhibition of the synthesis of prostaglandin and other mediators of inflammation. Diclofenac acts as anti-inflammatory and analgesic agent in the treatment of topical symptoms of rheumatic and non-rheumatic pains of the locomotor apparatus.

PHARMACOKINETIC PROPERTIES

Absorption: After topical application, diclofenac is well-absorbed into the subcutaneous layers of the skin.

Distribution: The diclofenac concentration was measured in plasma and tissue and synovial fluid after topical administration in the hands and knees joints. Maximum plasma concentration was about 100 times lower than after oral administration.

Biotransformation: Biotransformation of diclofenac involves partly glucuronidation of the intact molecule, and mainly single and multiple hydroxylations, most of which are converted to glucuronide conjugates (hydroxyl-glucuronates).

Elimination: Diclofenac and its metabolites are excreted mainly in the urine.

INDICATIONS

Voren Gel is indicated in adults and adolescents aged 12 years and over as anti-inflammatory and analgesic agent in the treatment of:

- Post-traumatic inflammation of the tendons, ligaments, muscles and joints, e.g. due to sprain, strains, and bruises.
- Localized form of soft tissue rheumatism, e.g. tendovaginitis, bursitis, shoulder and hand syndrome and periarthopathy.
- Localized form of degenerative rheumatism e.g. osteoarthritis of the peripheral joints and vertebral column.

DOSAGE AND ADMINISTRATION**Adults and adolescents aged 12 years and over:**

- Apply thin layers of **Voren Gel** in the affected area, 3-4 times daily according to the need of the situation (about 2-4 g, quantity as big as a cherry or a walnut) and rub gently.
- The treatment duration depends on the indications and the patient's response to the treatment. It is recommended that the treatment should be evaluated 7 days after its beginning.
- In adolescents aged 12 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patients/parents of the adolescent is/are advised to consult a doctor.
- **Voren Gel** can be used as additional treatment to the oral administration of non-steroidal anti-inflammatory drugs.

Children and adolescents aged below 12 years: There are insufficient data on efficacy and safety available for the children and adolescents below 12 years of age.

Hepatic and renal impairment: No dosage adjustment is required in patients with hepatic impairment. **Voren Gel** is contraindicated in patients with renal impairment.

Elderly: The usual adult dosage may be used.

Method of administration

- Cutaneous use.
- Apply on healthy skin only.
- After application, the hands should be washed, unless these are being treated.

CONTRAINDICATIONS

- Hypersensitivity to the active substance or to any of the excipients.
- Patients with or without chronic asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or NSAIDs.
- The use in children and adolescents aged less than 12 years is contraindicated.
- Third trimester of pregnancy.
- Patients with renal impairment.

WARNINGS AND PRECAUTIONS

- The occurrence of systemic undesirable effects with the topical use of diclofenac is low when compared with the frequency of undesirable effects with the oral use of diclofenac.
- The possibility of systemic adverse events from application of topical diclofenac cannot be excluded if the preparation is used on large areas of skin and over a prolonged period.
- Cutaneous safety of NSAIDs: Serious skin reactions, some of them fatal, have been reported very rarely, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, associated with the administration of NSAIDs. Apparently the risk of occurrence of these reactions is higher at the beginning of the treatment and in most cases these reactions are manifested during the first month of treatment. Concomitant

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

- **Voren Gel** should be discontinued at the first signs of rash, mucosal injuries or other hypersensitivity manifestations.
- Topical diclofenac 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.
- The area treated with Diclofenac gel should not be exposed to sunlight.
- Topical diclofenac can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

DRUG INTERACTION

The occurrence of drug interactions should be considered in patients applying diclofenac, particularly if in large areas of the skin and for prolonged periods, in combination with ACE inhibitors and Angiotensin II Antagonists. Consequently, this drug combination should be used with caution, especially in elderly patients.

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:

- 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.
- Diclofenac is contraindicated during the third trimester of pregnancy.

Breast-feeding

The product should only be used during lactation under advice from a healthcare professional.

Effects on ability to drive and use machines

Cutaneous application of topical diclofenac has no or negligible influence on the ability to drive and use machines.

UNDESIRABLE EFFECTS

Adverse reactions 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.

Adverse Drug Reaction	Frequency
Urticaria, angioneurotic oedema, rash pustular and asthma	Very rare
Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus	Common
Dermatitis bullous	Rare
Photosensitivity reaction	Very rare
Burning sensation at the application site Dry skin	Not known

Although less likely with the topical administration, some side effects normally associated with systemically administered diclofenac may also occur. The prolonged use of diclofenac in a relatively extensive area can cause systemic side effects such as nausea, vomiting, diarrhoea or epigastric pain.

OVERDOSE

The low systemic absorption of topical diclofenac renders overdose very unlikely.

PRESENTATION

Voren Gel 1%: 30gm pack

INSTRUCTIONS:

Keep out of reach of children.

Do not store over 30°C.

Protect from heat, light and avoid freezing.

For external use only.

Do not use on open wounds.

ہدایات:

بچوں کی پہنچ سے دور رکھیں۔

دوا کو ۳۰°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

گرمی، روشنی اور خمد ہونے سے بچائیں۔

صرف بیرونی استعمال کے لئے ہے۔

کھلے ہوئے زخم پر مت لگائیں۔



Marketed by:
Asian Continental (Pvt.) Ltd.
D-32, S.I.T.E. II, Super Highway,
Karachi-Pakistan.



Manufactured by:
Wimits Pharmaceuticals (Pvt.) Ltd.
129-Sunder Industrial Estate, Lahore.
M. L. No.: 00789
Reg. No.: 116650