

Front

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Topical analgesic, antiinflammatory agent

## KENOFEN<sup>®</sup> GEL (KETOPROFEN)



KENOFEN is a topical preparation of gel type which contains ketoprofen, one of NSAIDS. KENOFEN is a new preparation which is manufactured with updated pharmaceutical technology patented globally at IL DONG Research Laboratory. It has excellent therapeutic effect in arthritis and its related conditions. KENOFEN is a clear and colourless gel.

### Composition

Each 1g contains

<b>Ketoprofen</b>	30.0mg
<b>Methylparaben</b>	1.7mg
<b>Propylparaben</b>	0.2mg

### Pharmacology

- Kenofen gel has excellent therapeutic effect in arthritis and its related conditions, while it has slight side effects.
- Kenofen gel is absorbed fast by gentle rubbing on sore area, it has excellent antiinflammatory and analgesic activities.
- Kenofen gel has no gastrointestinal disorders caused by oral administration, is scarcely absorbed into blood. So it is very safe.

### Pharmacokinetics

In order to reduce the systemic side effects and gastrointestinal irritation of ketoprofen after its oral administration, it was formulated as a 3% ketoprofen gel (Kenofen Gel) with Pluronic F-127.

The pharmacokinetic characteristics of Kenofen Gel was evaluated following its transdermal application on the dorsal skin of rats at the dose of 9mg/kg in reference to those of existing 3% ketoprofen gels.

Even though the maximum concentration of 810ng / ml was reached at 6 hrs postdose, the plasma concentration was kept almost constant until 24hrs postdose, which suggested that ketoprofen was released continuously from the gel during this period. The bioavailability of Kenofen Gel was two times higher than those of existing 3% ketoprofen gels, based on the calculated area under the plasma concentration-time curves after the percutaneous administration.

### Indications

Local treatment of painful disorders of the osteo-articular and muscular system of rheumatic or traumatic origin: contusions, distortions, muscle strains, stiff neck, lumbago.

### Dosage and Administration



Apply a thin layer of gel 1 to 3 times daily onto the area of affected skin, gently massaging to help absorption.

Apply 1-3 times

### Precautions

- The gel should be used with caution in patients with severe renal impairment and should not be applied to open wound or lesions of the skin, or near the eyes.
- Patients should be advised against excessive exposure to sunlight of area treated in order to avoid possibility of photosensitivity.

### Contraindications :

- 1) Patients with hypersensitivity to this drug.
- 2) Patients with a history of aspirin asthma. (Induced asthma caused by NASIDs).

### Careful administration :

Patients with bronchial asthma.

### Adverse reactions :

- 1) Skin : Such symptoms as reddening, rash, itching, dry skin, tingling or swelling may occur rarely, discontinue the medication if such symptoms are observed.
- 2) Hypersensitivity : Anaphylactoid symptoms (hives, difficult breathing) may occur rarely, discontinue the medication if such symptoms are observed.

### General precautions :

- 1) It should be kept in mind that the treatment with an antiinflammatory and analgesic drug is not causal therapy but a symptomatic therapy.
- 2) This drug may mask the usual signs and symptoms of skin infection. Therefore this drug should be used with an appropriate antibacterial agent for infectious inflammation. Close observation and careful administration is also needed under this condition.
- 3) Therapeutic measures expect for medication should be considered when this drug is used to treat chronic disease (arthritis deformans etc.)

### Use during pregnancy :

The safety in pregnant women has not been established, therefore it should be administered only in cases of real necessity.

### Use in lactating mothers :

It is recommended not be used in lactating mothers.

### Pediatric use :

The safety in children has not been established.

### Cautions for applying :

- 1) Do not administer for ophthalmic use.
- 2) In case of epidermolysis, please be cautious in using it, because you may feel skin tingling temporarily.
- 3) Do not occlude dressing.

### Drug interactions :

No interactions of Kenofen gel with other drugs have been reported. It is, however, opportune to monitor patients under treatment with coumarinic substances. Incompatibilities : No incompatibilities with other drugs are known.

### Overdosage :

If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. However, if they occur, treatment should be supportive and symptomatic.

### Storage

Store in a tight container at 25°C.  
Shelf Life : 3 years

Package : 50g / Tube

Product Registration Holder:

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