

KefenTech *Plaster*

[Product name]

Kefentech Plaster

[Composition]

Each sheet (10cm×7cm, 2.36g) contains; Ketoprofen 30mg

[Appearance]

This medicine has lint fabric spread with colorless, transparent paste, which is covered with film-coated thin paper.

[Indication]

It is indicated for the treatment of signs and symptoms of the following.

- arthritis deformans (rheumatoid arthritis).
- Periarthritis humero-scapularis (frozen, painful or stiff shoulder).
- Peritendinitis & tendonitis
- Muscular pain
- Pain, swelling resulted from trauma (contusion, distortion etc)

[Interaction]

This is a topical plaster, and interaction with other medicaments is not known.

[Overdosage and treatment]

There is no report of overdosage. Remove the plaster immediately if there is any side effect.

[Pharmacodynamics/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 with pluronic F-127. The pharmacokinetics of ketoprofen 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 6hrs 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 ketoprofen 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.

[Precautions]**1. Contra-Indications**

- 1) Patients with a previous history of hypersensitivity to ketoprofen
- 2) Patients with aspirin asthma (i.e. induction of asthma by non-steroidal anti-inflammatory analgesics) or its previous history

2. KefenTech plaster should be given carefully in following;

- 1) Patients with bronchial asthma

3. Adverse Reactions

- 1) Skin: Redness, rash, pruritus skin dryness & irritation may infrequently occur and swelling rarely occur. Treatment should be discontinued in the event of such symptoms.
- 2) Hypersensitivity: Anaphylactoid symptoms (e.g. urticaria, dyspnea) may rarely occur. In the event of such symptoms, this product should be discontinued.

4. General Cautions

KefenTech *Plaster*

- 1) It should be noted that treatment by anti-inflammatory analgesics is symptomatic, not causal.
- 2) Ketoprofen may suppress the manifestation of dermal infections. Therefore close supervision and careful administration are required with concurrent adequate antibiotics or antifungal agent in case that ketoprofen is used for inflammation caused by infections.
- 3) In case of using this product for chronic disease (such as arthritis deformans, etc.), it should be administered to the patients as the adjunction with other anti-inflammatory agents. Patients should be observed carefully and manifestation of adverse reactions should be observed.

5. Use in Pregnancy

Safety for pregnant women has not been established. Therefore prolonged use of KefenTech plaster with large dose or to wide affected part should be avoided in women who are or may be pregnant.

6. Pediatric Use

Safety for children has not been established.

7. Cautions in Application

- 1) Do not use to the eye or mucosa.
- 2) Temporary pain or irritation of skin may occur when the epidermis is broken. Therefore caution in use is required.
- 3) Do not use for occlusive dressing.

[Storage Condition]

Do not store above 30 °C

[Packing Unit]

1 sheet (10cm×7cm)×6,7,8,9,10



Manufactured by

JEIL HEALTH SCIENCE INC.

Product Registration Holder:

SOMEDICO SDN BHD

No.3 Jalan TSB1, Taman Industri Sg Buloh 47000 Sungai Buloh Selangor Malaysia

Revised June 2022