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280 x 170

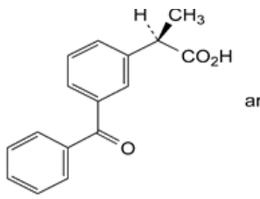
# KETOPRO

**(KETOPROFEN GEL BP 2.5 % W/W)**
**Ketoprofen**

**KETOPRO** (Ketoprofen Gel BP 2.5 % w/w) contains 25 mg/g, active substance Ketoprofen.

Ketoprofen is a nonsteroidal anti-inflammatory drug (NSAID) with anti-inflammatory analgesic and antipyretic properties and is chemically described as (2*RS*)-2-(3-Benzoylphenyl) propanoic acid.

The molecular formula of Ketoprofen is $C_{16}H_{14}O_3$ with a molecular weight of 254.3. The structural formula of Ketoprofen
(CAS-22071-15-4) is:




and enantiomer

**DESCRIPTION**
A clear transparent homogenous gel, free of agglomerates.

**PHARMACOLOGY**
***Pharmacotherapeutic category:*** Non-steroidal anti-inflammatory of the propionics group, derivative of aryl-carboxylic acid for topical use.
***ATC Code***: M02A A10
Ketoprofen is a non-steroidal anti-inflammatory of the propionics group, derivative of arylcarboxylic acid.
It has anti-inflammatory and analgesic properties.

**PHARMACOKINETICS**
Applied locally in the form of a gel, Ketoprofen is absorbed very gradually and is not accumulated in the body. The systemic passage of the gel compared to that of the oral formulations of Ketoprofen is around 5 per cent, which enables a local effect to be obtained without systemic incidence.

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

**CONTRAINDICATIONS**
Known allergy to Ketoprofen, to substances of similar activity to aspirin.
History of hypersensitivity to any of the excipients.
History of any photosensitivity reactions.
Known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAIDs (including when taken by mouth).
History of skin allergy to ketoprofen, tiaprofenic acid, fenobrate or UV blocker or perfumes.
Sun exposure, even in the case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation.
Third trimester of pregnancy.
Patholgical skin changes such as dermatosis, eczema or acne, infected skin lesions, or open wounds.
Not to be applied neither to mucous membranes, anal or genital areas, nor on the eyes.
Not to be used with occlusive dressings.
Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene-containing products.

**WARNINGS AND PRECAUTIONS**
For topical use only.

Risk of GI Ulceration, Bleeding and Perforation with NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy.
Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.
Hands should be washed thoroughly before use and immediately after each application of product (unless they are the area being treated).
It is recommended to protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitisation.

Topical application of large amounts may result in systemic effects including hypersensitivity and asthma (renal disease has also been reported).
The recommended length of treatment should not be exceeded due to the risk of developing contact dermatitis and photosensitivity reactions which increases over time.
Patients with asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis have a higher risk of allergy to aspirin and/or NSAIDs than the rest of the population.
The safety and efficacy of ketoprofen gel in children have not been established.

Although systemic effects are minimal, the gel should be used with caution in patients with reduced heart, liver or renal function: isolated cases of systemic adverse reactions consisting of renal affections have been reported.
Should a skin rash occur after gel application, treatment must be stopped.

Areas of skin treated with Ketoprofen 2.5% Gel should not be exposed to direct sunlight, or solarium ultraviolet light, either during treatment or for two weeks following treatment discontinuation, in order to avoid phototoxicity reactions and photoallergy.

Keep the gel away from naked flames. Do not incinerate.

**INTERACTIONS WITH OTHER MEDICINES**

Interactions are unlikely, as serum concentrations following topical application are low. However concurrent aspirin or other NSAIDs may result in increased incidence of adverse reaction. Serious interactions have been recorded after the use of high dose methotrexate with non-steroidal anti-inflammatory agents, including ketoprofen, when administered by the systemic route.

**PREGNANCY AND LACTATION**
***Pregnancy:***
Pregnancy
No embryopathic effects have been demonstrated in animals and there is epidemiological evidence of the safety of ketoprofen in human pregnancy. Nevertheless, it is recommended that ketoprofen should be avoided during the first and second trimester of pregnancy.
During the third trimester of pregnancy, all prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the foetus. At the end of the pregnancy, prolonged bleeding time in both mother and child may occur. Non-steroidal anti-inflammatory drugs may also delay labour. Therefore, ketoprofen is contraindicated during the last trimester of pregnancy.
Lactation
Trace amounts of ketoprofen are excreted in breast milk following oral administration, therefore the gel should not be used during breast feeding.
**ADVERSE EFFECTS**
Infections and infestations:
Not known: Secondary impetigo
Blood and lymphatic system disorders
*Not known:* Eosinophilia
Immune system disorders
*Not known:* anaphylactic shock, angioedema, hypersensitivity reactions
Eye disorders
*Not known:* Eyelid oedema
Vascular disorders
*Not known:* Vasculitis
Gastrointestinal disorders
Not known: Peptic ulcer, gastrointestinal bleeding, diarrhoea, lip oedema
Skin and subcutaneous tissue disorders
*Uncommon:* Local skin reactions such as rash, erythema, eczema, pruritus and burning sensation, application site burn.
*Rare:* Photosensitisation, urticaria, bullous/contact/exfoliative/vesicular dermatitis, phlyctenular eczema, blister, photosensitivity reaction, allergic reaction, skin exfoliation, skin oedema.
Renal and urinary disorders
*Very rare:* Cases of aggravation of previous renal insufficiency, acute renal failure
General disorders and administration site conditions
*Not known:* Pyrexia
Injury, poisoning and procedural complications
*Not known:* Wound complication

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**
Effect on Ability to drive and use machines are not known.

**OVERDOSAGE AND TREATMENT**
Overdosage is unlikely to be caused by topical administration. 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 at a temperature not exceeding 30°C, in a dry place.
Protect from light. Do not freeze.
Keep out of reach of children.

**DOSAGE FORM AND PACKAGING**

**Dosage Form**
Semi-solid (Gel for topical use)

**Pack Size: 30 g or 50 g**

**Manufactured by :**
Mepro Pharmaceuticals Pvt. Ltd. Unit-II,
Q Road, Phase-IV, G.I.D.C, Wadhwan City - 363 035,
Surendranagar, Gujarat, INDIA

**Registration No. : MAL20046125AZ**

**NAME AND ADDRESS OF MALAYSIAN PRODUCT REGISTRATION HOLDER**
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A-17-7, BLOCK A, JAYA ONE,
NO. 72A, JALAN PROFESOR DIRAJA UNGKU AZIZ,
SEKSYEN 13, 46200 PETALING JAYA
MALAYSIA

D0351 R2

**DATE OF REVISION OF PACKAGE INSERT**
December 2022