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# Ketoprofen

## Ketofen Gel

25 mg/g (2.5%) Gel

Non-Steroidal Anti-inflammatory Drug

## FORMULATION

Each gram contains: Ketoprofen ..... 25 mg
Preservatives:
Methyl Hydroxybenzoate .....1 mg
Propyl Hydroxybenzoate ..... 100 mcg

## DESCRIPTION

Colourless gel.

## INDICATIONS

Ketoprofen gel is used in musculoskeletal and joint disorders such as ankylosing spondylitis, osteoarthritis, and rheumatoid arthritis, and in peri-articular disorders such as bursitis and tendinitis.

## PHARMACOKINETICS

Applied locally, ketoprofen is absorbed very slowly and there is no accumulation in the body. The bioavailability of the gel relative to oral forms of ketoprofen is around 5%. The low systemic bioavailability suggests that systemic effects are unlikely.

## DOSAGE AND ADMINISTRATION

Adult and children above 5 years:
Apply 2 to 4 times daily to the skin in the painful or inflamed region. Apply gently and massage well to ensure gel penetration.
The gel can be used with an occlusive dressing.
The total dose should not exceed 20 g per day regardless of the number of areas affected. Ketoprofen gel should be avoided in children below 5 years.

## CONTRAINDICATIONS

Ketoprofen gel should be avoided in patients with hypersensitivity to ketoprofen, exudative dermatoses, eczema, sores and infected skin lesions or broken skin. Do not apply to the mucous membranes or eyes.

Absolute contraindications:
Not to be given to those patients who have history of:

- Stroke: cerebrovascular accident, CVA
- Heart attack: myocardial infarction, MI
- Coronary artery bypass graft, CABG
- Uncontrolled hypertension
- Congetsive heart failure (CHF) NYHA II-IV

## PRECAUTIONS

- Should skin rash occur after gel application, treatment should be stopped.
- Ketoprofen gel should be avoided in children below 5 years.
- Keep the gel away from naked flames and do not incinerate.
- Although systemic effects are minimal, the gel should be used with caution in patients with severe renal impairment.
- Areas of skin treated with Ketoprofen gel should not be exposed directly to sunlight, or solarium ultraviolet light, either during treatment or for two weeks following treatment discontinuation.

## ADVERSE EFFECTS

- Skin reactions including photosensitivity reactions, pruritus, localised erythema have occurred rarely. These are usually mild and resolve after cessation of the gel.
- Cases of more severe reactions such as bullous or phylcytenar eczema which may spread or become generalised have occurred rarely.

## WARNING

- Contraindication in patient with history of hypersensitivity to ASA or any other NSAIDs.
- NSAIDs are contraindicated in patients with previous or active peptic ulceration.
- Use with caution in patients with cardiac, liver and renal disease. Dose adjustment like using the lowest effective dose and monitoring of renal and liver functions should be instituted.

## DRUG INTERACTIONS

Interactions are unlikely as serum concentrations following topical administration are low.

## OVERDOSE

Overdose is unlikely by topical application.
If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. Treatment is otherwise supportive and symptomatic.

## USE IN PREGNANCY AND LACTATION

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 to avoid ketoprofen unless considered essential, in which case, it should be discontinued within 1 week of expected confinement since NSAIDs might cause premature closure of the ductus arteriosus or persistent pulmonary hypertension in the neonate. They may also delay labour.
Trace amounts of ketoprofen are excreted in breast milk, therefore, avoid the use of ketoprofen during breast feeding unless considered essential.

Caution: Food, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

Availability: Aluminium tube 25 mg/g x 30 g.
Storage: Store at temperatures not exceeding 25˚C.

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Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Imported & Distributed by: HOVID Inc
Unit B 7th Floor Karina Bldg., 33 Shaw Boulevard,
Pasig City, Philippines.

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