KETOPRO (KETOPROFEN GEL BP 2.5%W/W)

Ketoprofen 2.5% w/w

What is in this leaflet

What is KETOPRO used for

KETOPRO is indicated for a local treatment of painful disorders of bones, joints and muscles of rheumatic or traumatic origin, example bruises, distortion, muscle strains, stiff neck, lower back pain.

How KETOPRO works

KETOPRO contains the active ingredient Ketoprofen. It is in the class of non-steroidal anti-inflammatory drugs (NSAIDs). It has anti-inflammatory and pain-relieving properties.

Before you use KETOPRO

-When you must not use it

Do not use this product if the following applies to you:

- Allergic (skin or other reactions such as asthma/ runny nose/itchy eyes) to Ketoprofen or any other drugs in the NSAIDs class, including when taken by mouth (e.g., Aspirin, Tiaprofenic acid) or Fenofibrate (drug used to treat high cholesterol) or UV blockers or perfumes
- Allergic to any of the inactive ingredients listed in this leaflet
- History of light-sensitivity reactions
- You will be exposed to strong UV rays (sunlight/ sun-beds) during and 2 weeks after treatment with this product
- Have skin conditions such as dermatosis (disease of skin without inflammation), eczema or acne, infected skin lesions or open wounds
- You are in your third trimester of pregnancy

Do not apply this gel on mucous membranes or at private areas.

Do not let this gel be in contact with your eyes.

Do not use this gel with non-breathable dressings.

If you experience any skin reactions while using this product (including use of this product with octocrylene containing products, an ingredient found in cosmetics and sunscreen), discontinue its use immediately.

Pregnancy and lactation:

It is recommended to avoid this product use during pregnancy and breastfeeding. If you are unsure, please consult your doctor/ pharmacist.

Avoid use if you are in your third trimester of pregnancy.

-Before you start to use it

Inform your doctor/ pharmacist about other medications you are taking before starting this medicine.

This medicine is for topical application only. Do not ingest this gel. Wash your hands properly before and after using this gel (unless the treatment area is your hand).

Do not exceed the recommended treatment period as advised by your doctor/pharmacist due to possibility of contact dermatitis (skin inflammation cause by the product) and photosensitivity.

There is a risk of gastro-intestinal ulceration, bleeding and perforation with NSAIDs use although unlikely with this product because it is applied topically. Be aware if you experience symptoms such as stomach discomfort while using this medication. Seek doctor/pharmacist advice if you experience such symptoms.

Protect the area being treated from sunlight during and two weeks after discontinuation of treatment to avoid any photosensitivity.

Although side effects are minimal, you should be careful with this product especially if you have a reduced heart, liver or kidney function. Speak to your doctor/pharmacist if you have any concerns.

If you develop a skin rash while using this gel, discontinue its use immediately.

-Taking other medications

Interactions are unlikely as this product is applied topically. However, if you are currently taking NSAIDs for pain, there is an increased incidence for a side effect.

If you are on an immune suppressive medication called Methotrexate, consult your doctor/pharmacist before using this product.

How to use KETOPRO

-How much to use

Apply a thin layer of gel onto affected area, 1 to 3 times a day. Massage the gel in gently.

-When to use it

Use as recommended by your doctor/pharmacist.

-How long to use it

Continue using KETOPRO for as long as your doctor/pharmacist recommends it.

-If you forget to use it

Consult your doctor/pharmacist on what you should do if you forget to use it.

Apply the missed dose as soon as you remember. If it is almost time for

your next dose, wait until then to apply the medicine and skip the missed dose. Do not apply a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Applying too much of this gel may cause systemic effects (effects seen if the same drug is taken internally) such as stomach upset, hypersensitivity and asthmatic attacks.

While you are using it

-Things you must do

Use this medicine exactly as your doctor/pharmacist has told you.

Tell all doctors/pharmacists/dentists treating you that you are taking KETOPRO.

Tell your doctor/pharmacist immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop using this medicine unless advised by your doctor/pharmacist.

Do not use take any new medicines without consulting your doctor/pharmacist.

Do not give KETOPRO to anyone else, even if they have the same symptoms or condition as you.

Keep this gel away from heat and fire. Do not destroy this product with fire.

-Things to be careful of

Driving and using machines:

Effects on driving and using machines are unknown.

Side effects

Like all medicines, KETOPRO can cause side effects, although not everybody gets them.

Visit your doctor/pharmacist immediately if you experience any side effects after using this medication.

Some side effects observed while on this medication are:

Uncommon: local skin reactions – rash, redness of skin, eczema, itchiness and burning sensation at application site.

Unknown frequency: secondary skin infection, increase in number of white blood cells called eosinophils, severe allergy known as anaphylactic shock, swelling beneath the skin, general allergic reactions, eyelid swelling, blood vessel inflammation, gastric ulcer, gastrointestinal bleeding, diarrhoea, lip swelling, fever and wound complication

Other rare side effects include – sensitivity/ reactions to light, itching of skin, skin inflammation, a form of eczema called phlyctenular eczema, blisters, allergic reaction, skin peeling or swelling.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of KETOPRO

-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.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

A clear, transparent homogenous gel, free of agglomerates.

-Ingredients

- Active ingredient(s)

  Ketoprofen 2.5% w/w

- Inactive ingredient(s)

  Carbopol 940, Methyl hydroxybenzoate (paraben), Propyl hydroxybenzoate (paraben), Diethylamine, Isopropyl alcohol BP, Propylene glycol BP and Purified water BP.

-MAL number

MAL20046125AZ

Manufacturer

Mepro Pharmaceuticals Pvt. Ltd.
Unit II, Q Road, Phase IV,
G.I.D.C., Wadhwan, Surendranagar,
Gujarat 363035, India

Product Registration Holder

Synercam (M) Sdn. Bhd.
A-17-7, BLOCK A, JAYA ONE,
NO. 72A, JALAN PROFESOR
DIRAJA UNGKU AZIZ,
SEKSYEN 13, 46200 PETALING
JAYA MALAYSIA

Date of revision

-29/12/2022

Serial Number

NPRA (R2) 20/021