

## Package leaflet: Information for the user

### **KETOPROFEN 2.5 % w/w GEL** **Ketoprofen 25 mg/g**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Ketoprofen Gel is and what it is used for
2. What you need to know before you use Ketoprofen Gel
3. How to use Ketoprofen Gel
4. Possible side effects
5. How to store Ketoprofen Gel
6. Contents of the pack and other information

#### **1. What Ketoprofen Gel is and what it is used for**

Ketoprofen Gel is a homogeneous and colourless gel for application to the surface of the skin only. It contains ketoprofen which belongs to a non-steroidal group of anti-inflammatory drugs (NSAIDs), like aspirin, which help to reduce pain and inflammation.

Ketoprofen Gel is used for pain relief in:

- soft tissue injuries including sports injuries and sprains and strains
- musculo-tendonitis
- swelling
- backache
- conditions affecting the joints and/or connective tissues e.g. arthritis (inflammation of the joints).

#### **2. What you need to know before you use Ketoprofen Gel**

##### **Do not use Ketoprofen Gel**

- If you have a history of allergy or hypersensitivity to Ketoprofen or to any of the other ingredients of Ketoprofen Gel (see section 6), tiaprofenic acid, fenofibrate, UV blockers or perfumes. Symptoms of this would include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you have ever had asthma, urticaria (skin rash), or runny nose and sneezing after taking aspirin or other NSAIDs
- On an area where you have any skin conditions, eczema or acne, open wounds or infections
- In your eyes, mouth, nose, or on the anal or genital areas; if this happens, **wash with plenty of clean water**
- If you are pregnant within your third trimester
- If you have a history of photosensitivity reactions/reactions to light

- On an area with an occlusive dressing.

Stop using Ketoprofen Gel immediately if you experience any skin reactions including skin reactions after co-application of octocrylene-containing products (octocrylene is one of the excipients included in several cosmetic and hygiene products such as shampoo, after-shave, shower-and bath-gels, skin creams, lipsticks, anti-ageing creams, make-up removers and hair sprays to delay photodegradation).

**⚠️ Protect your skin from sunlight even on a bright but cloudy day. Do not use sun beds. This applies during treatment and for two weeks after stopping.**

### **Warnings and precautions**

Talk to your doctor before using Ketoprofen Gel:

- If you have heart, liver or kidney problems.
- The use of large amounts of Ketoprofen Gel may give rise to side effects such as hypersensitivity and asthma.
- Exposure to sunlight (even hazy) or to UV light of areas treated with Ketoprofen Gel can cause serious skin reactions (Photosensitisation). Therefore it is necessary to:
  - protect treated areas by wearing clothing during treatment and for two weeks after stopping treatment, to avoid any risk of photosensitisation.
  - wash hands thoroughly after each application of Ketoprofen Gel.
- Treatment should be discontinued immediately upon development of any skin reaction after application of Ketoprofen Gel.
- Avoid direct sunlight and solarium (sunbeds) during and for 2 weeks after treatment.
- Do not exceed the recommended length of treatment.
- If you have asthma as well as a persistent runny nose, sinusitis or nasal polyps, you may have a higher risk of being allergic to aspirin or similar medicines than other people.
- If you have an infection - please see heading “Infections” below.

Consult your doctor if you develop any skin reaction after using Ketoprofen Gel. If you have to go to a hospital, tell the medical staff that you are using this product.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Ketoprofen Gel.

### **Infections**

Ketoprofen Gel may hide signs of infections such as fever and pain. It is therefore possible that Ketoprofen Gel may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, especially those for pain relief, such as aspirin or other NSAIDs or Methotrexate used for the treatment of some types of cancer or psoriasis.

### **Pregnancy and breast-feeding**

Do not use if you are in the last 3 months of pregnancy. It may affect your baby.

Do not use this medicine if you are breast-feeding. This is because small amounts may pass into mothers` milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### 3. How to use Ketoprofen Gel

#### FOR EXTERNAL USE ONLY

Always use Ketoprofen Gel exactly as your doctor has told you. Your doctor will tell you how much to apply and how often, but you must check with your doctor if you are not sure.

#### **Do not exceed the stated dose.**

For application to the **surface of the skin** only:

1. Wash your hands thoroughly before use.
2. Unscrew the cap, turn it upside down and use the spike of the cap to puncture the top of the tube.
3. Apply the correct dose. Massage the gel gently into the painful or inflamed area to ensure absorption into the skin, and there may be a slight cooling effect as the gel is applied. Apply 2 to 4 g of Ketoprofen Gel (equivalent to a 5-10 cm strip) to the affected area two to four times a day. **Do not apply more than 15 g** of gel (equivalent to approximately 35 cm strip) in any one day.

The usual dose is

Adults, the elderly and children over 15 years:	Apply 5 - 10 cm of the gel to the affected area 2 - 4 times a day for up to 7 days.
Children under 15 years:	Not recommended.

4. Replace the cap tightly immediately after use.
5. Wash your hands again, unless your hands are being treated with the gel.
6. Once applied, **do not cover** the area with a dressing or plaster.
7. **If your symptoms remain at the end of 7 days, stop your treatment and consult your doctor or pharmacist.**

Do not exceed the recommended maximum daily dose of 15 g (equivalent to a 35 cm strip) of Ketoprofen Gel in one day.

If you do, you may experience allergy (hypersensitivity) and asthma or other effects including kidney disease.

If you get the gel in your eyes, mouth, nose or on the anal or genital areas, wash with plenty of water.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

#### **If you use more Ketoprofen Gel than you should**

If you apply more than 15 g of gel in any one day, you may experience an allergic reaction (hypersensitivity), asthma or other effects including kidney disease. If you accidentally use more gel than recommended or if you or your child accidentally swallow the gel, contact your

doctor or nearest hospital casualty department immediately. Take any remaining gel with you and keep it in the original packaging to help identification.

### **If you forget to use Ketoprofen Gel**

If you miss a treatment, apply the gel as soon as you remember, but do not use more than 4 times a day.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

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

**Stop using Ketoprofen Gel immediately and see your doctor or go to the hospital straight away if:**

- You have an allergic reaction following application of the product. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue (frequency not known).
- severe skin reactions during exposure to sunlight such as blistering or eczema of the eyes which may spread or become generalized (frequency rare)
- a serious allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing (anaphylactic shock) (frequency not known)
- You have flu-like symptoms at the same time, such as fever, chills or aching muscles (frequency not known).

**Tell your doctor or pharmacist if you have any of the following side effects. Also tell them if you notice any side effects not listed in this leaflet.**

**Uncommon side effects (may affect up to 1 in 100 people) are:**

- Local skin reactions such as redness, eczema, itching or burning sensation

**Rare side effects (may affect up to 1 in 1,000 people) are:**

- Skin reaction to light or sunlamps (photosensitivity)
- Skin rashes, blisters, red lumps or eczema

**Very rare side effects (may affect up to 1 in 10,000 people) are:**

- Worsening of existing kidney problems, interruption of normal functioning of the kidneys

**Not known (frequency cannot be estimated from the available data)**

Other effects, which depend on the amount of gel applied, the extent of the area that is treated, skin thickness, length of treatment, and the use of an air-tight or water-tight dressing, are the following:

- Higher than normal levels of eosinophils (a particular kind of blood cell)
- Inflammation of blood vessels (known as vasculitis)
- Stomach ulcer, which may be bleeding, and diarrhoea
- Higher than normal body temperature
- Complication of wounds in patients with increased vulnerability to infection

Elderly people are generally more likely to suffer from side effects of Non-Steroidal Anti-Inflammatory Drugs (the drug class to which Ketoprofen Gel belongs).

## **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Ketoprofen Gel**

Keep Ketoprofen Gel away from naked flames.

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package and keep the tube in the outer carton. Do not use this medicine after the expiry date stated on the tube/carton.

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.

## **6. Contents of the pack and other information**

### **What Ketoprofen Gel contains**

- The **active substance** is ketoprofen and the gel contains 25 mg in every 1 g.
- The **other ingredients** are carbomer, triethanolamine, lavender essential oil, ethanol and purified water.

### **What Ketoprofen Gel looks like and contents of the pack**

The gel is homogeneous and colourless and is available in tubes containing 50 g or 100 g. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder/Manufacturer:**

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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