

# Ketoland 2.5% GEL

Ketoprofen 2.5% Gel



**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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**What is in this leaflet**

1. What Ketoland Gel is and what it is used for
2. What you need to know before you use Ketoland Gel
3. How to use Ketoland Gel
4. Possible side effects
5. How to store Ketoland Gel
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**1. WHAT KETOLAND GEL IS AND WHAT IT IS USED FOR**

The name of your medicine is Ketoland 2.5% Gel (called Ketoland Gel in this leaflet). Ketoland gel contains the active ingredient Ketoprofen . This belongs to a group of medicines called 'Non-Steroidal Anti-Inflammatory Drugs' (NSAIDs). It works by blocking some chemicals in your body that normally cause inflammation and reducing pain.

Ketoland Gel is used to treat the swelling, pain, heat, redness and stiffness in your joints and muscles in the following: arthritis (inflammation of the joints), pain from injuries such as sports injuries, sprains and strains.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE KETOLAND GEL**

**Do not use this medicine and tell your doctor if:**

you are allergic (hypersensitive) to Ketoland , tiaprofenic acid, fenofibrate, UV blockers (sun creams) or perfumes, aspirin any other Non-Steroidal Anti-Inflammatory Drug (NSAIDs) such as ibuprofen or indometacin, any of the other ingredients of Ketoland Gel (listed in Section 6 below).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. Further do not use it if you have or have ever had asthma or other allergies, you have or ever had eczema (scaly and itching rashes), you have sore, broken or infected skin, you are in the last 3 months of pregnancy (see 'Pregnancy and breast-feeding' below), you are applying the gel on sensitive skin such as interior of the nose, anal or genital areas and eyes or under an airtight dressing.

**Stop using Ketoland Gel immediately** if you experience any skin reaction including skin reactions after co-application of octocrylene-containing products (octocrylene is one of the excipients of 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 in order to delay photo-degradation).

**Check with your doctor or pharmacist before using your medicine if:** you have heart, liver or kidney problems.

Following exposure to sunlight (even hazy) or to UV light (sun-beds), areas treated with Ketoland Gel can cause serious skin reactions (photosensitisation). Therefore, it is necessary to protect treated areas by wearing clothing during the treatment and for two weeks after stopping treatment to avoid any risk of photosensitisation.

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

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Ketoland Gel can affect the way some other medicines work. Also, some medicines can affect the way Ketoland Gel works.

In particular, tell your doctor if you are taking any of the following: Metotrexate, used for some types of cancer or psoriasis, oral anticoagulants (blood thinning medicines).

**Pregnancy and breast-feeding**

Talk to your doctor before taking this medicine if you are less than or up to 6 months pregnant, might become pregnant, or think you may be pregnant.

Do not use this medicine if you are in the last 3 months of pregnancy.

You should not breast-feed if you are using Ketoland Gel because small amounts may pass into mothers' milk.

**3. HOW TO USE KETOLAND GEL**

Always use Ketoland Gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This medicine is applied on the skin.

It must not be put on sensitive skin such as the mouth, genitals, back passage or eyes.

Do not cover the gel with a dressing. Do not mix this gel with anything else.

Avoid direct sunlight, ultraviolet rays and sun-beds and protect the treated region with clothing when outdoors, even in the absence of direct sun.

Careful and prolonged hand washing should be carried out after each use of the gel.

**Recommended dosage and administration**

*Adults and elderly*

Apply to the painful area two to four times a day for up to 7 days as directed. Do not use for longer than directed as this can increase your chances of getting side effects such as skin reactions to light (photosensitivity) or inflammation of the skin (dermatitis).

The usual dose is 15 grams a day (approximately 28 centimetres) of the gel onto the painful area.

*Use in Children*

Ketoland Gel is not recommended for use in children.

#### **How to use this medicine**

Wash your hands before you apply the medicine  
Remove the cap from the tube  
Squeeze out the required amount onto your palm  
Rub gently into the painful area  
Wash your hands again  
Replace the cap on the tube  
Do not cover the area. Allow it to dry.

If you use more gel than you should it is unlikely to cause a problem. If you or someone else accidentally swallows Ketoland Gel, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget a dose, use it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

#### **4. POSSIBLE SIDE EFFECTS**

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

**Stop taking your medicine and see your doctor or go to a 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).

*The following rare side effects (affecting less than 1 in 1000 patients) have been reported:*

Severe skin reactions during exposure to sunlight such as blistering or eczema of the eyes which may spread or become generalized.

*Uncommon side effects (affecting less than 1 in 100 patients) reported were:* local skin reactions such as redness, eczema, itching or burning sensation.

*Rare side effects (affecting less than 1 in 1000) reported were:* skin reaction to light or sunlamps (photosensitivity) and skin rashes, blisters, red lumps or eczema.

*Very rare side effects (affecting less than 1 in 10,000 patients) reported were:* worsening of existing kidney problems

Tell your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

#### **5. HOW TO STORE KETOLAND GEL**

Do not use Ketoland Gel after the expiry date which is stated on the carton and the tube after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the gel away from naked flames. Do not incinerate.

Keep out of the reach and sight of children.

#### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

Carton containing 1 tube of 60 g of Ketoland 2,5 % Gel, with leaflet. Ketoland 2.5% Gel is a colourless transparent gel.

##### **Composition:**

100 g of gel contain: Ketoland 2,5 g – Excipients: ethanol, glycerol, diethanolamine, carbomer 940, methyl-p-hydroxybenzoate, propyl-p-hydroxybenzoate, purified water.