

Topical ketoprofen and risk of photosensitivity reactions: reminder of risk minimisation measures

Product name	Licence number	Prescription status	Presentations available	Licence holder
Powergel® 2.5% Gel	PL 10649/0001	POM	50 g tube/dispenser 100 g tube/dispenser	A Menarini Industrie Farmaceutiche Riunite S.R.L.
Ketoprofen 2.5% w/w Gel	PL 04917/0069	POM	50 g tube 100g tube	Pinewood Laboratories Limited
Oruvail® 2.5% w/w Gel	PL 04425/0627	POM	100 g tube	Sanofi
Tiloket Gel 2.5%	PL 11311/0127	POM	50 g tube 100 g tube	Tillomed Laboratories Limited

Dear Healthcare Professional,

Photosensitivity reactions (including phototoxicity and photoallergic reactions) are important and potentially serious side effects to topical ketoprofen. We remind you to take the following steps to minimise the risk of these reactions.

Action points

Prescribers:

- Strictly follow the contraindications when prescribing topical ketoprofen.

Prescribers and pharmacists:

- Discuss, as appropriate, the attached 'Checklist for Prescribers' and 'Information Sheet For Patients' (see links below) to ensure you fully understand the risks and how to minimise them.
- Remind patients to take the following steps to minimise the risk of photosensitivity reactions:
 - i. wash hands thoroughly after each application of the gel
 - ii. do not expose treated areas of skin to sunlight (even when weather conditions are cloudy), or to UVA during treatment and for two weeks after stopping treatment
 - iii. protect treated areas of skin from sunlight by wearing clothing
 - iv. do not use topical ketoprofen under occlusive bandaging
 - v. stop treatment immediately if you have **any** kind of skin reaction to this product
- Discuss the 'Information Sheet For Patients' (see links below) with patients – make sure they fully understand the risks of skin reactions and how to minimise them.
- Give all patients a copy of the 'Information Sheet For Patients' – tell them to carefully read this and the Patient Information Leaflet that comes with the gel.
- Report any suspected side effects to this or any other medicine to the MHRA through the Yellow Card Scheme (see details below).

Further information

Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). In topical formulation, ketoprofen is licensed to treat benign indications in traumatology and rheumatology.

It is known that topical ketoprofen may trigger allergic contact reactions including photoallergy, some of which have been serious, leading to hospitalisation. European medicines regulators have reviewed the cutaneous side effects and provided the above risk minimisation recommendations for prescribers and pharmacists.

The current prescribing advice can be found at <http://www.medicines.org.uk/emc/> for Powergel (Menarini), Oruvail (Sanofi) and Ketoprofen 2.5% w/w Gel (Pinewood). For Tiloket (Tillomed), please see <http://www.mhra.gov.uk/spc-pil/?subsName=KETOPROFEN&pageID=SecondLevel> and <http://www.tillomed.com/> (for 'Checklist for prescribers' and 'Information Sheet For Patients').

The content of this letter has been agreed with the Medicines and Healthcare products Regulatory Agency (MHRA).

Call for reporting suspected side effects

Please report suspected adverse drug reactions (ADRs) to this or any other medicine to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle

It is easiest and quickest to report ADRs online via the Yellow Cards website: www.mhra.gov.uk/yellowcard. Alternatively, prepaid Yellow Cards for reporting are available:





- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800~731-6789
- or by downloading and printing a form from the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates and product brand name.

In addition, this information may be reported to the relevant licence holder. The contact details are given below.

Licence holders' contact details

Should you have any questions or require further information regarding ketoprofen, please contact the relevant licence holder.

<p>A Menarini Farmaceutica Internazionale SRL Dr Jit Solanki</p>  <p>Head of Medical Affairs Menarini House, Mercury Park, Wycombe Lane, Wooburn Green Buckinghamshire HP10 0HH Tel: 0800 085 8678 Fax: 01628 856402 Medical Information: menarini@medinformation.co.uk Website: www.menarini.co.uk</p>	<p>Pinewood Laboratories Limited Gordon Urquhart</p>  <p>Qualified Person for Pharmacovigilance c/o Wockhardt UK Limited Ash Road North Wrexham LL13 9UF Tel: 01978 661 261 Fax: 01978 669 430 Medical Information: drug.safety@wockhardt.co.uk Website: www.wockhardt.co.uk</p>
<p>Sanofi Dr Timir Patel</p>  <p>Medical Manager 1 Onslow Street, Guildford Surrey GU1 4YS Tel: 0845 372 7101 Fax: 01483 535432 Medical Information: uk-medicalinformation@sanofi.com Website: http://www.sanofi.co.uk</p>	<p>Tillomed Laboratories Limited Alan C. Robinson</p>  <p>Sales and Marketing Director 3 Howard Road, Eaton Socon, St Neots Cambridgeshire PE19 8ET Tel: 01480 402 400 or 0800 970 6115 Fax: 0800 970 6114 Medical Information: info@tillomed.co.uk Website: www.tillomed.co.uk</p>

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Checklist for the prescriber: minimising the risk of photosensitivity with topical ketoprofen

Dear Healthcare professional,

Photosensitivity reactions (including phototoxicity and photoallergy) are an important side effect of topical ketoprofen (brand names: Oruvail, Powergel, Tiloket and Ketoprofen 2.5% Gel).

Checklist – complete before prescribing:

1. verify that the patient does not have any phototoxicity- or photoallergy-related contraindications when prescribing any brand of ketoprofen 2.5% gel
2. explain to patients the steps they need to take to minimise the risk of photosensitivity reactions
3. check that patients understand the risk of photosensitivity and the steps they need to take to minimise this risk

1. Contraindications related to phototoxicity and photoallergy of ketoprofen 2.5% gel

Before prescribing any brand of ketoprofen 2.5% gel, ensure that the patient satisfies the following conditions:

- No history of photosensitivity reaction
- No history of skin allergy to
 - o ketoprofen
 - o tiaprofenic acid
 - o fenofibrate
 - o UV blockers (particularly those containing octocrylene)
 - o perfumes
- No history of hypersensitivity reactions (eg symptoms of asthma or allergic rhinitis) to:
 - o ketoprofen
 - o tiaprofenic acid
 - o acetylsalicylic acid (aspirin)
 - o any other nonsteroidal anti-inflammatory drug (NSAID)
 - o fenofibrate

2. Risk minimisation measures

Tell patients to take the following precautions; ensure patients understand the importance of these steps:

- Wash hands thoroughly after every time you apply the gel
- Do not expose treated areas of skin to sunlight (even when the weather is cloudy) or to UV light from a sunbed or solarium
- When outdoors, protect treated areas of skin with clothing. Do this during treatment and for 2 weeks after stopping treatment
- Do not use the gel under an airtight bandage. Do not use the gel for longer than prescribed
- Stop using the gel immediately and tell your prescriber if you have **any** skin reaction to it or to products containing octocrylene (an ingredient in several cosmetic and hygiene products such as sun blockers, shampoo, after-shave, shower- and bath-gels, skin creams, lipsticks, anti-ageing creams, make-up removers, hair sprays, etc)

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Information sheet for patients minimising the risk of skin reactions with topical ketoprofen

Ketoprofen 2.5% gel is for external use only and is available under the brand names Oruvail, Powergel, Tiloket, or is simply called Ketoprofen Gel. Your prescriber should have already informed you about the precautions to take while using this gel; however, here is a reminder.

You might have a serious skin reaction (eg severe eczema) if you expose the areas of skin treated with this gel to sunlight (even when the weather is cloudy) or to UV light from a sunbed or solarium. These effects can spread from where you applied the gel to other parts of the skin.

Take the following steps to minimise your risk of developing these skin reactions while using **any brand** of ketoprofen gel:

- Do not use ketoprofen 2.5% gel if you have ever had an allergic reaction to any of the following:
 - any brand of ketoprofen gel
 - tiaprofenic acid
 - fenofibrate
 - UV blockers (sun blockers, particularly those containing octocrylene)
 - perfumes
- Wash your hands thoroughly after every time you apply the gel.
- Do not expose areas of skin treated with the gel to sunlight (even when the weather is cloudy) or to UV light from a sunbed or solarium.
- When outdoors, protect areas of the skin treated with the gel with clothing. Do this during treatment and for 2 weeks after stopping treatment.
- Do not use the gel under an airtight bandage.
- Do not use the gel for longer than stated on your prescription.
- Stop using the gel immediately and tell your prescriber if you have **any** skin reaction to it or to products that contain octocrylene (one of the ingredients of several cosmetic and hygiene products such as sun blockers, shampoo, after-shave, shower- and bath-gels, skin creams, lipsticks, anti-ageing creams, make-up removers, hair sprays, etc).

For further information, please contact your prescriber or your pharmacist.

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