# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Ketoprofen 2.5% w/w Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoprofen 25 mg/g

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gel

Homogenous transparent gel with an odour of lavender and alcohol

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Symptomatic relief of pain in such conditions as soft tissue injuries, including sport injuries, sprains, strains, musculo-tendonitis, swelling, backache and rheumatic pain.

### 4.2 Posology and method of administration

For cutaneous use.

Penetration of the gel by gentle and prolonged massage on the painful or inflamed surface for up to seven days.

Two to four daily applications of approximately 2 to 4 g gel, representing approximately 5 to 10 cm. The usual maximum dose is 15 g per day.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4).

Children (under 15 years): Not recommended, as safety in children has not been established.

## 4.3 Contraindications

- Known allergy to Ketoprofen, to substances of similar activity to aspirin.
- History of hypersensitivity to any of the excipients listed in section 6.1.
- History of any photosensitivity reactions.
- Known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAIDs (including when taken by mouth).
- History of skin allergy to ketoprofen, tiaprofenic acid, fenobrate or UV blocker or perfumes.
- Sun exposure, even in the case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation (see Section 4.4. Special warnings and precautions for use).
- Third trimester of pregnancy (see section 4.6).
- Patholgical skin changes such as dermatosis, eczema or acne, infected skin lesions, or open wounds.
- Not to be applied neither to mucous membranes, anal or genital areas, nor on the eyes.
- Not to be used with occlusive dressings.
- Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene-containing products.

## 4.4 Special warnings and precautions for use

For topical use only.

Hands should be washed thoroughly before use and immediately after each application of product (unless they are the area being treated).

It is recommended to protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitisation.

Topical application of large amounts may result in systemic effects including hypersensitivity and asthma (renal disease has also been reported).

The recommended length of treatment should not be exceeded (see section 4.2) due to the risk of developing contact dermatitis and photosensitivity reactions which increases over time.

Serious skin reactions, such as Stevens-Johnson Syndrome (SJS), have been reported in association with the use of NSAIDs, including ketoprofen gel. Patients should be informed about the signs and symptoms of serious skin

manifestations. Treatment should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Masking of symptoms of underlying infections
Ketoprofen can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When ketoprofen is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

Patients with asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis have a higher risk of allergy to aspirin and/or NSAIDs than the rest of the population.

The safety and efficacy of ketoprofen gel in children have not been established.

Although systemic effects are minimal, the gel should be used with caution in patients with reduced heart, liver or renal function: isolated cases of systemic adverse reactions consisting of renal affections have been reported.

Should a skin rash occur after gel application, treatment must be stopped.

Areas of skin treated with Ketoprofen 2.5 % Gel should not be exposed to direct sunlight, or solarium ultraviolet light, either during treatment or for two weeks following treatment discontinuation, in order to avoid phototoxicity reactions and photoallergy.

Keep the gel away from naked flames. Do not incinerate.

<u>The label will state:</u>

Do not exceed the stated dose.

For external use only.

Keep out of the sight and reach of children.

If symptoms persist consult your doctor or pharmacist.

Do not use if you are allergic to ketoprofen or any of the ingredients, aspirin or any other pain killers.

Do not expose treated areas to sunlight (even hazy) including UV from solarium during the treatment and the 2 weeks after its discontinuation.

Consult your doctor before use if:

You are taking aspirin or any other pain-relieving medication.

You are pregnant or breast feeding.

## 4.5 Interaction with other medicinal products and other forms of interaction

Interactions are unlikely, as serum concentrations following topical application are low. However concurrent aspirin or other NSAIDs may result in increased incidence of adverse reaction. Serious interactions have been recorded after the use of high dose methotrexate with non-steroidal anti-inflammatory agents, including ketoprofen, when administered by the systemic route.

### *4.6 Pregnancy and lactation*

Pregnancy

There are no clinical data from the use of topical forms of ketoprofen during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic ketoprofen exposure reached after topical administration can be harmful to an embryo/foetus. During the first and second trimester of pregnancy, ketoprofen should not be used unless clearly necessary. If used, the dose should be kept as low as possible.

During the third trimester of pregnancy, all prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the foetus. At the end of the pregnancy, prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, ketoprofen is contraindicated during the last trimester of pregnancy (see section 4.3).

Lactation

Trace amounts of ketoprofen are excreted in breast milk following oral administration, therefore the gel should not be used during breast feeding.

### 4.7 Effects on ability to drive and use machines

Not applicable.

### 4.8 Undesirable effects

The following CIOMS frequency rating is used: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10 000 to <1/1000); very rare (<1/10 000), not known (cannot be estimated from the available data).

Infections and infestations:
*Not known:* Secondary impetigo

Blood and lymphatic system disorders
*Not known:* Eosinophilia

Immune system disorders
*Not known:* anaphylactic shock, angioedema, hypersensitivity reactions

Eye disorders
*Not known:* Eyelid oedema

Vascular disorders
*Not known:* Vasculitis

Gastrointestinal disorders
*Not known:* Peptic ulcer, gastrointestinal bleeding, diarrhoea, lip oedema

Skin and subcutaneous tissue disorders
*Uncommon:* Local skin reactions such as rash, erythema, eczema, pruritus and burning sensation, application site burn.
*Rare:* Photosensitisation, urticaria, bullous/contact/exfoliative/vesicular dermatitis, phlyctenular eczema, blister, photosensitivity reaction, allergic reaction, skin exfoliation, skin oedema.
*Not known:* Stevens-Johnson syndrome.

Renal and urinary disorders
*Very rare:* Cases of aggravation of previous renal insufficiency, acute renal failure

General disorders and administration site conditions
*Not known:* Pyrexia

Injury, poisoning and procedural complications
*Not known:* Wound complication

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

Overdosage is unlikely to be caused by topical administration. If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. However, if they occur, treatment should be supportive and symptomatic.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Ketoprofen is a non-steroidal anti-inflammatory of the propionics group, derivative of aryl-carboxylic acid.

It has anti-inflammatory and analgesic properties.

### 5.2 Pharmacokinetic properties

Applied locally in the form of a gel, ketoprofen is absorbed very gradually and is not accumulated in the body. The systemic passage of the gel compared to that of the oral formulations of ketoprofen is around 5 per cent, which enables a local effect to be obtained without systemic incidence.

### 5.3 Preclinical safety data

The main acute side effect seen during the safety studies after oral, sc and ip routes is the ulcerogenic potential. The target organs for chronic toxicity are the gastro-intestinal tract, the kidney and, to a lesser degree the liver. Due to low systemic passage of ketoprofen from the gel such safety data are not relevant for local administration. Studies on the local tolerance have shown that ketoprofen is well tolerated.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer

Triethanolamine

Lavender essential oil

Ethanol 95%

Purified water

### 6.2 Incompatibilities

None stated.

### 6.3 Shelf life

30 months

### 6.4 Special precautions for storage

Do not store above 25ºC.

### 6.5 Nature and contents of container

Varnished aluminium tube – polyethylene screw cap.

50g or 100g.

### 6.6 Special precautions for disposal

None stated.

## 7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited,
*Trading as: Pinewood Healthcare*
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland.

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 04917/0069

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/10/2024

## 10 DATE OF REVISION OF THE TEXT

09/10/2024