

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Tiloket 2.5% Gel (Ketoprofen)

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

1 What Tiloket Gel is and what it is used for

The name of this medicine is Tiloket Gel. It contains ketoprofen, which belongs to the group of medicines known as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). It works by reducing inflammation and relieving pain.

Tiloket Gel is used to treat the swelling, pain, heat, redness and stiffness in your joints and muscles in the following:

- Soft tissue injury, including rheumatic pain
- Sports injuries
- Sprains, strains, joint pain
- Ligaments, muscle and tendon injuries as well as swelling and backache

2 What you need to know before you use Tiloket Gel

Do not use Tiloket Gel:

- If you are allergic to Ketoprofen, other NSAIDs or any of the other ingredients of this medicine (listed in section 6)
- If you suffer from allergic reactions such as difficulty breathing, swelling of the face, throat or tongue, "runny nose" (rhinitis) or wheals on the skin (urticaria) after using aspirin, tiaprofenic acid or other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen or indometacin, or fenofibrate (a medicine used to lower blood cholesterol)
- If you have a history of increased sensitivity of the skin to sunlight (photosensitivity)
- If you have a history of skin allergy to ketoprofen, fenofibrate, tiaprofenic acid, UV blockers (sun creams) or perfume
- If you suffer from skin problems including eczema, acne, infected skin lesions, wounds, broken skin and sores
- If you are in the last 3 months of pregnancy

Do not use Tiloket Gel on the eyes, nostrils, mouth, back passage or genital area or with air/water-tight wound dressings

(Graphic: Explanation symbol)

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 Tiloket Gel:

- If you have problems with your heart, liver or kidneys

- If you have asthma and also long term (chronic) runny nose (rhinitis), inflammation of the sinuses (sinusitis) and/or nasal polyps

Recommended length of treatment should not be exceeded as prolonged use or use of large amounts of Tiloket Gel may increase the risk of developing inflammation of the skin and photosensitivity reactions

Stop using Tiloket Gel immediately if you experience any skin reaction such as a rash including skin reactions after using it with products containing octocrylene (ingredient 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 hairsprays).

Other medicines and Tiloket Gel:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

In particular, tell your doctor if you are taking the following:

Methotrexate, used for some types of cancer or psoriasis (chronic skin disease which causes scaly pink patches)

Pregnancy and breast-feeding

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

Pregnancy

- Do **not** use Tiloket Gel if you are in the last 3 months of pregnancy. You should not use Tiloket Gel during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.
- Oral forms (e.g. tablets) of ketoprofen can cause adverse effects in your unborn baby. It is not known if the same risk applies to Tiloket Gel when it is used on the skin.

Breast-feeding

Do **not** use Tiloket Gel if you are breast-feeding as a small amount may pass into the breast milk.

3 How to use Tiloket Gel

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Tiloket Gel is for **external use** only.
- It must not be applied to eyes, mouth, nostrils, genitals, back passage or broken skin
- Protect treated areas by wearing clothing during the treatment and for two weeks after you have stopped to avoid any risk of sensitivity of the skin to sunlight (photosensitivity)
- Avoid direct sunlight, UV rays and sun beds
- Do not cover the gel with a dressing

How to apply

- Wash your hands thoroughly before and after use unless the hands are being treated.
- Unscrew the plastic cap and using the spike inside the cap, pierce the top of the tube.
- Apply to the skin of the affected area as directed.
- Replace plastic cap immediately after use.

Adults:

- 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 under 15 years of age

Tiloket Gel is not recommended.

If you apply more Tiloket Gel than you should

If you accidentally apply more gel than you should and/or you develop a rash or other skin irritation, contact your doctor or pharmacist as soon as possible for advice.

If you forget to apply Tiloket Gel

Apply it as soon as you remember, unless it is nearly time for your next application. If you miss an application, do **not** apply double the amount of gel to make up for a forgotten application.

If you stop using Tiloket Gel

It is important that you keep using Tiloket Gel for as long as your doctor has told you to.

If you swallow Tiloket Gel

If the gel is accidentally swallowed, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or tube with you.

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

4 Possible side effects

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

Serious Side Effects

Stop using Tiloket Gel and seek medical advice immediately if you develop:

- Allergic reactions: swelling of the face, throat or tongue, difficulty breathing or dizziness (anaphylaxis)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Frequent wheezing, breathlessness, abdominal pain, diarrhoea, fever, cough and rashes due to an increase in certain white blood cells (eosinophilia)
- Localised skin reactions such as redness, swelling, itching and blisters
- Burning sensation including on application site

Other Side Effects

Uncommon: may affect up to 1 in 100 people

The following side effects are usually mild and disappear after stopping treatment with Tiloket Gel:

- Severe itching (pruritus)
- Skin rashes (erythema) and inflammation of the skin (eczema)

Rare: may affect up to 1 in 1,000 people

- Skin rash or inflammation (dermatitis)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Skin rashes with the formation of wheals (urticaria)

Very rare: may affect less than 1 in 10,000 people

- Worsening of existing kidney problems or kidney failure

Not known: frequency cannot be estimated from the available data

- Contagious skin infection that causes sores and blisters (impetigo)
- Swelling of the eyelids and/or lips
- Inflammation of blood vessels (vasculitis)
- Stomach ulcer
- Bleeding from the stomach, gums or bottom
- Diarrhoea
- Fever (pyrexia)
- Complication of wounds

Elderly people are particularly susceptible to the side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 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 Tiloket Gel

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the carton/tube after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Keep the tube in the original container. Once opened, use within 1 month.
- Keep Tiloket Gel away from naked flames and do not burn.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Tiloket Gel contains:

Tiloket Gel contains 2.5% w/w of Ketoprofen.

The other ingredients are: carbomer, triethanolamine, lavender essential oil, ethanol and purified water.

What Tiloket Gel looks like and contents of the pack:

Tiloket Gel is a homogeneous transparent gel with an odour of alcohol and lavender.

Tiloket Gel is available in:

A 50g and 100g tube with a plastic screw cap.

Not all packs sizes may be marketed.

Product Licence Number: PL 11311/0127

Marketing Authorisation Holder & Manufacturer:

Marketing Authorisation Holder

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