

PACKAGE LEAFLET: INFORMATION FOR THE USER

POWERGEL 2.5 %W/W 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 Powergel is and what it is used for
2. What you need to know before you use Powergel
3. How to use Powergel
4. Possible side effects
5. How to store Powergel
6. Contents of the pack and other information

1. What Powergel is and what it is used for

Powergel contains a medicine called ketoprofen. Powergel belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These reduce inflammation and relieve pain.

Powergel is used to relieve the pain of soft tissue injuries, and acute strains and sprains. Powergel should only be used by adults and children over 12 years of age.

2. What you need to know before you use Powergel

Do not use Powergel:

- If you are allergic to ketoprofen or to any of the other ingredients of this medicine (listed in Section 6)
- If you are allergic to UV blockers (sun creams) or perfumes
- If you are allergic to aspirin, other NSAIDs (eg ibuprofen) or any medicines for pain relief or inflammation including tiaprofenic acid
- If you are allergic to fenofibrate (a medicine used to lower blood cholesterol)
- If you have had wheezing (asthma), runny nose (rhinitis) or an itchy rash (hives) after taking aspirin or other NSAIDs (eg ibuprofen)
- If you intend to use it on skin conditions such as eczema or acne, an open or infected wound, abscess, ulcer or tumour
- If the area to be treated is near the eyes
- If you are in the last 3 months of pregnancy. (see Pregnancy, breast-feeding and fertility section)
- If the area is near mucous membranes (eg lips, vagina).

Stop using Powergel immediately if you experience any skin reaction including reactions after co-application with octocrylene containing products (octocrylene is an ingredient used 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 in order to delay product breakdown due to sunlight).



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

Warnings and precautions

Talk to your doctor before using Powergel:

- If you have heart, liver or kidney problems.
- The use of large amounts of Powergel may give rise to side effects such as hypersensitivity and asthma.
- Exposure to the sun (even hazy) or to UV from a sunbed or solarium of areas treated with Powergel can induce potentially serious skin reactions (photosensitisation). Therefore it is necessary to:
 - protect treated areas by wearing clothing during treatment and for two weeks following its discontinuation to avoid any risk of photosensitisation.
 - wash your hands thoroughly after each application of Powergel.
- Treatment should be discontinued immediately upon development of any skin reaction such as rash after application of Powergel.
- 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.

Children and adolescents

The safety and efficacy of Powergel in children has not been established.

Other medicines and Powergel

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, e.g. oral anticoagulants (blood thinning medicines).

Powergel with food, drink and alcohol

No known effects

Pregnancy, breast-feeding and fertility

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.

Do not use Powergel if you are in the last 3 months of pregnancy. You should not use Powergel 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 Powergel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Powergel when it is used on the skin.

Driving and using machines

It has not been established if Powergel could affect your ability to drive and use machinery.

Powergel contains Neroli fragrance and Lavandin fragrance

This medicine contains fragrances with citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool that may cause allergic reactions.

Powergel contains ethanol

This medicine contains 307 mg alcohol (ethanol) in each g of gel. Ethanol may cause a burning sensation on damaged skin.

3. How to use Powergel

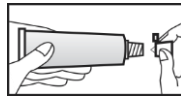
Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is a length of gel 5-10 cm (2-4 inches) long (3-6 pushes of the pump dispenser) applied to the skin of the affected area two or three times daily.

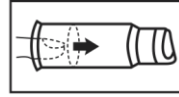
How to apply Powergel

It is important to use Powergel as directed:

- tube: unscrew the cap and pierce the aluminium seal with the point in the top of the cap.



- pump dispenser: when using the pump dispenser for the first time, press the top of the dispenser several times or push the bottom until the gel is released. Keep the dispenser in a horizontal position during use (see the pictures below).



How and where to use Powergel

- Powergel is for external use only
- Gently massage the gel on the area you need to treat
- Wash your hands immediately after use
- Do not apply Powergel to sore, broken or infected skin
- Do not use Powergel near the eyes, mouth, nostrils, anal and genital regions
- Stop using Powergel if you get a rash, itchy or sensitive skin after use
- Do not use with an air-tight or water-tight dressing (i.e. do not bandage, wrap, or cover the area with a plastic dressing)
- Do not use too much of this medicine.

Protection from the sun and sunbeds

- Do not expose the skin that has been treated with Powergel to direct sunlight or sunbeds during treatment or for the following 2 weeks.

Use in children and adolescents

Do not use in children under 12 years of age.

How long should you use Powergel for?

Do not use Powergel for more than 10 days in a row.

If your symptoms persist after 10 days, tell your doctor.

If you use more Powergel than you should

When Powergel is externally applied (on the skin), very little reaches the blood. For this reason overdose effects are most unlikely.

If you forget to use Powergel

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.

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

4. Possible side effects

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

Stop using Powergel and tell your doctor if you notice any of the following side-effects:

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

- Localised allergic skin reactions such as redness, swelling, itching and blisters: in some severe cases, these might also spread beyond the area of application
- Sensation of burning skin

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

- Severe skin reactions (similar to severe sunburn) during exposure to sunlight
- Increased sensitivity of your skin to sunlight.
- Skin vesicles (skin blisters)
- Itchy skin reactions (skin rash)
- Cases of more severe forms of eczema which may spread or become generalized have occurred rarely.

Very rare side effects (may affect less than 1 in 1,000 people) are:

- Kidney insufficiency (New or worsening of a pre-existing kidney disorders).

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:

- Allergic reactions, which may lead to difficulty breathing and/or may be very severe (anaphylaxis). If this occurs, seek medical aid immediately.
- A kind of skin infection (known as impetigo)
- Higher than normal levels of eosinophils (a particular kind of blood cell)
- Hypersensitivity (a type of allergic reaction)
- Swelling of the eyelids or of the lips
- Inflammation of blood vessels (known as vasculitis)
- Stomach ulcer, which may be bleeding, and diarrhoea
- Higher than normal body temperature
- Complication of wounds

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

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. Website: 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 Powergel

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use Powergel after the expiry date which is stated on the carton and tube/dispenser. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Powergel contains

The active substance is ketoprofen.

The other ingredients are: purified water, ethanol, triethanolamine, carbomer, neroli fragrance (containing citral, citronellols, farnesol, geraniol, d-limonene and linalool), lavandin fragrance (containing coumarin, geraniol, d-limonene and linalool).

What Powergel looks like and contents of the pack

Powergel is a gel of mucilaginous consistency, colourless or slightly yellowish, almost transparent, with an aromatic odour. Powergel is available in the following pack sizes - 50 g and 100 g tube, 50 g and 100 g pump dispenser.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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