

Package leaflet: Information for the patient

Ibuprofen 10% w/w Gel

ibuprofen

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet:

1. What Ibuprofen 10% w/w Gel is and what it is used for
2. What you need to know before you use Ibuprofen 10% w/w Gel
3. How to use Ibuprofen 10% w/w Gel
4. Possible side effects
5. How to store Ibuprofen 10% w/w Gel
6. Contents of the pack and other information

1. What Ibuprofen 10% w/w Gel is and what it is used for

Ibuprofen 10% w/w Gel contains Ibuprofen and belongs to a group of medicines called nonsteroid anti-inflammatory drugs (NSAID's).

Ibuprofen 10% w/w Gel is used to treat a number of painful conditions affecting the joints and muscles such as back pain, sprains, strains and other sport injuries.

2. What you need to know before you use Ibuprofen 10% w/w Gel

Do not use Ibuprofen 10% w/w Gel:

- If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic aspirin or similar medicines (e.g NSAIDs).
- If you are asthmatic, or suffer from rhinitis (allergic runny nose) or urticaria (hives) and have ever had a bad reaction to aspirin, ibuprofen or other NSAIDs in the past.
- On broken, damaged, infected or diseased skin.

Warnings and precautions

Talk to your doctor or pharmacist before using Ibuprofen 10% w/w Gel, if you have any of the below:

- If you have had an ulcer or some other problem affecting your stomach, or intestines in the past
- If you have any kidney problems
- If you suffer from bronchial asthma or any allergic disease.
- When applying the gel to the skin be careful to avoid the eyes, lips and mouth, and any damaged skin.

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash.
- Do not use on the genital area.
- Do not apply a dressing to the same area after using the gel
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

If you develop a rash after using the gel stop using it further.

Ibuprofen 10% w/w Gel is FOR APPLICATION TO THE SKIN ONLY

Children

Not recommended for children under 12 years

Other medicines and Ibuprofen 10% w/w Gel:

Tell your doctor or pharmacist if you are taking or have recently taken or might use any other medicines.

The effect of this medicine may affect or be affected by taking the following medicines at the same time:

- Medicines to lower your blood pressure (e.g. atenolol)
- Medicines used to thin the blood (e.g. warfarin)
- Aspirin or other NSAIDS (including other forms of Ibuprofen), used for pain and inflammation.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using any medicine.

You should not use Ibuprofen 10% w/w Gel if you are pregnant or breast-feeding.

Driving and using machines

Ibuprofen 10% w/w Gel should not affect the ability to drive or use machines.

Ibuprofen 10% w/w Gel contains benzyl alcohol and sodium:

This medicine contains 1.25 mg benzyl alcohol in each 125mg, which is equivalent to 0.01mg/mg. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains less than 1 mmol sodium (23 mg) per 125mg, that is to say essentially 'sodium-free'.

3. How to use Ibuprofen 10% w/w Gel

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

Ibuprofen 10% w/w Gel is designed for topical (on the skin) application only. Never take the gel by mouth.

Check the seal is intact before first use (invert cap to break seal). If the seal is not intact, do not use the gel.

The recommended dose is:

Adults, the elderly and children over 12 years: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel (equivalent to 50 mg to 125 mg ibuprofen) from the tube on affected area. Massage until absorbed. Do not use more frequently than every four hours and no more than 4 times a day in any 24 hour period.

Ibuprofen 10% w/w Gel should only be used on healthy, unbroken skin. Do not use it on or near cuts or grazes or under dressings such as plasters. Do not let any gel come in contact with your eyes. If it does, rinse your eyes with cold water and consult your doctor. Hands should be washed after applying Ibuprofen 10% w/w gel, unless they are the site of treatment. Do not use the gel on the genital area.

If the condition does not improve after two weeks use, or becomes worse at any time, speak to your doctor or pharmacist.

Use in Children : Ibuprofen 10% w/w Gel is not recommended for use in children under 12 years.

If you accidentally swallow any Ibuprofen 10% w/w Gel, rinse out your mouth thoroughly. In case of an upset stomach, speak to your doctor or pharmacist.

If you forget to use your Ibuprofen 10% w/w Gel: If you miss a dose, just carry on with the next dose as normal. Do not apply a double dose to make up for a forgotten dose.

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.

- **All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness (asthma), worsening of existing asthma, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching or reddening (especially affecting your whole body), sore or weeping spots and burning feeling or peeling, blistering of skin should be reported to a doctor immediately.**
- **If you notice any signs of kidney problems (particularly in people who have a history of kidney disease) should contact your doctor straightaway.**

Other side effects with the following frequency include:

Uncommon (may affect up to 1 in 100 people)

- Abdominal Pain (pains in your stomach)
- Indigestion.

Not known (frequency cannot be estimated from the available data)

- Skin becomes sensitive to light.

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 Ibuprofen 10% w/w Gel

Keep this medicine out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and 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 outer carton in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Ibuprofen 10% w/w Gel contains

The active substance is Ibuprofen. The other ingredients are hydroxyethylcellulose (E1525), sodium hydroxide (E524), benzyl alcohol (E1519), isopropyl alcohol, purified water.

What Ibuprofen 10% w/w Gel looks like and contents of the pack

Ibuprofen 10% w/w Gel is clear or slightly opalescent, colourless or almost colourless gel supplied in aluminium tubes containing 30g or 40g gel. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Mercury Pharma Group Ltd, Capital House, 85 King William Street, London EC4N 7BL, UK

Manufacturer: Farmasierra Manufacturing S.L. Carretera De Irun KM 26,200 28709, SAN Sebastian De Los Reyes, Madrid, Spain.

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