

PATIENT INFORMATION LEAFLET

Ibuprofen 10% w/w Gel

Ibuprofen

Read all of this leaflet carefully before you start taking this medicine.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT IS IBUPROFEN 10% W/W GEL AND WHAT IT IS USED FOR

Ibuprofen 10% w/w Gel contains ibuprofen and belongs to a group of medicines called non-steroid anti-inflammatory drugs (NSAID's). These medicines reduce pain and inflammation, and bring down a high temperature.

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. It is also used for the relief of pain caused by mild to moderate arthritic conditions and nerve pain (neuralgia).

2. BEFORE YOU USE IBUPROFEN 10% W/W GEL

Do not use Ibuprofen 10% w/w Gel:

- If you are allergic to ibuprofen, aspirin or similar medicines (e.g. NSAIDs) or any of the other ingredients in this gel (listed at the end of this leaflet)
- If you are asthmatic, or suffer from rhinitis (allergic runny nose) or urticaria (hives)
- On broken, damaged, infected or diseased skin.
- If you are in the last 3 months of pregnancy

Take special care with Ibuprofen 10% w/w Gel:

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash
- You have had an ulcer or some other problem affecting your stomach or intestines in the past
- You have asthma or wheezing attacks (or if you have had asthma in the past)
- You have any kidney problems
- If you develop a rash after using the gel stop using it any further
- If you suffer from bronchial asthma or any allergic disease
- 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.
- Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Ibuprofen 10% w/w Gel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If any of the above apply to you, only use this product on advice from your doctor or pharmacist.

IBUPROFEN 10% W/W GEL IS FOR EXTERNAL USE ONLY.

Taking/Using other medicines:

Can you take Ibuprofen 10% w/w Gel with other medicines?

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicine, even those not prescribed by a doctor.

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

Please tell your doctor or pharmacist if you are taking any of the above, or have recently taken any other medicine - even those not prescribed.

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 or pharmacist for advice before using this medicine.

Do not use Ibuprofen 10% w/w Gel if you are in the last 3 months of pregnancy. You should not use Ibuprofen 10% w/w 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 Ibuprofen 10% w/w Gel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Ibuprofen 10% w/w Gel when it is used on the skin.

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

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

3. HOW TO USE IBUPROFEN 10% W/W GEL

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

Always use Ibuprofen 10% w/w Gel exactly as this leaflet tells you. You should check with your doctor or pharmacist if you are not sure. Check the seal is intact before first use (invert cap to break seal).

Adults: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel from the tube on affected area.

Massage until absorbed. This dose should not be repeated more frequently than every four hours and no more than four times a day in any 24 hour period. The amount of gel squeezed would be equivalent to 50 to 125mg of ibuprofen.

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. Also, do not use it on the genital area.

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.

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

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

If the gel is accidentally swallowed:

If you accidentally swallow any Ibuprofen 10% w/w Gel, rinse out your mouth thoroughly and contact your doctor, or nearest hospital, as soon as possible. If swallowed, the gel may cause an upset stomach.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines Ibuprofen 10% w/w Gel can cause side effects, although not everybody gets them.

- **All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.**
- **Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].**
- **Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).**
- **A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).**

Other Side effects include:

- Itching or reddening of the skin
- Abdominal Pain (pains in your stomach) or other abnormal stomach symptoms
- A burning feeling
- Sore or weeping spots
- Kidney problems (particularly in people who have a history of kidney disease)
- Skin becomes sensitive to light – frequency unknown.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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

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 sight and reach of children.

Do not use Ibuprofen 10% w/w Gel after the expiry date which is stated on the tube. The expiry date refers to the last day of that month. It should be stored in a cool, dry place, below 25°C. Keep the tube tightly closed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Remember:

This medicine is for you. Never give this medicine to someone else, it could harm them, even if their symptoms seem the same as yours.

6. FURTHER INFORMATION

What Ibuprofen 10% w/w Gel contains:

The active substance is ibuprofen. Other ingredients are hydroxyethylcellulose, sodium hydroxide, benzyl alcohol, isopropyl alcohol, purified water.

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

Ibuprofen 10% w/w Gel is supplied in aluminium tubes containing 100g gel.

Marketing Authorisation Holder:

Mercury Pharma Group Ltd.,
Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, UK

Manufacturer:

Farmasierra Manufacturing S.L.
Carretera De Irun KM 26,200, 28709, SAN
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