

Package leaflet: Information for the patient
Ibuprofen Pain relief gel 5% w/w
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. See section 4.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

This product is called Ibuprofen Pain relief gel 5% w/w. It will be referred to as Ibuprofen 5% gel in the rest of the patient information leaflet.

What is in this leaflet:

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

1. What is Ibuprofen 5% gel and what it is used for

Ibuprofen 5% 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 5% gel is used to treat a number of painful conditions affecting the joints and muscles, such as backache, rheumatic and muscular pain, sprains, strains and sports injuries. It is also used to treat pain from non-serious arthritic conditions and nerve pain (neuralgia).

2. What you need to know before you use Ibuprofen 5% gel

Do not use Ibuprofen 5% gel:

- If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to aspirin or similar medicines (e.g NSAIDs)
- 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.

Warnings and precautions

Take special care with Ibuprofen 5% Gel:

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 5% Gel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or pharmacist before using Ibuprofen 5% gel, if you have any of the below:

- Protect treated areas from direct sunlight to avoid any sensitivity reaction, e.g. a rash
- If you suffer from bronchial asthma or any allergic disease
- If you have had an ulcer or some other problem affecting your stomach or intestines in the past
- If you have asthma or wheezing attacks (or if you have had asthma in the past)
- If you have any kidney problems
- If you develop a rash after using the gel stop using it any further
- 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.

USE THIS MEDICINE ONLY ON YOUR SKIN

Children

Not recommended for children under 12 years

Other medicines and Ibuprofen 5% gel:

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 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 5% Gel if you are in the last 3 months of pregnancy. You should not use Ibuprofen 5% 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 5% Gel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Ibuprofen 5% Gel when it is used on the skin.

You should not use Ibuprofen 5% gel if you are breast-feeding.

Driving and using machines:

Ibuprofen 5% gel should not affect the ability to drive or use machines.

Ibuprofen 5% gel contains benzyl alcohol:

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.

3. How to use Ibuprofen 5% gel

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

Ibuprofen 5% 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).

The recommended dose is:

Adults: Squeeze 4 to 10cm (i.e. 1.6 to 4 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 5% 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 5% 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.

Use in children: Ibuprofen 5% gel is not recommended for use in children under 12 years.

If the gel is accidentally swallowed:

If you accidentally swallow any Ibuprofen 5% 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 5% 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.

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, 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 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.**
- **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 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, 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 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 5% 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 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.

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.

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. Contents of the pack and other Information

What Ibuprofen 5% gel contains:

The active substance is ibuprofen. Other ingredients are hydroxyethylcellulose, sodium

hydroxide, benzyl alcohol, isopropyl alcohol, purified water.

What Ibuprofen 5% gel looks like and contents of the pack

Ibuprofen 5% gel is clear or slightly opalescent, colourless or almost colourless gel supplied in aluminium tubes containing 100g gel

Marketing Authorisation Holder:

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

Manufacturer:

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

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