

PATIENT INFORMATION LEAFLET

IBUPROFEN 5% GEL

Read all of this leaflet carefully before you start taking 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 is 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

WHAT IS IN THIS LEAFLET

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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 (NSAIDs). 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.

2 WHAT YOU NEED TO KNOW BEFORE YOU USE IBUPROFEN 5% GEL

DO NOT use Ibuprofen 5% 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

Take special care with Ibuprofen 5% Gel

- 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

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

IBUPROFEN 5% GEL IS FOR EXTERNAL USE ONLY

Other medicines and Ibuprofen 5% Gel

Can you use Ibuprofen 5% Gel with other medicines?

Tell 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, 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

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

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

3 HOW TO USE IBUPROFEN 5% GEL

Ibuprofen 5% Gel is designed for topical (on the skin) application only. Never take the gel by mouth.

Always use Ibuprofen 5% 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).

Further information overleaf.

Adults: Squeeze 4 to 10cm (i.e. 1.6 to 4 inches) of gel from the tube and rub into the affected area 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.

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.

4 POSSIBLE SIDE EFFECTS

Like all medicines Ibuprofen 5% 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.

Side effects include:

- Itching or reddening of the skin
- A burning feeling
- Sore or weeping spots
- Kidney problems (particularly in people who have a history of kidney disease)
- Abdominal Pain (pains in your stomach) or other abnormal stomach symptoms

If any of the side effects get 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 5% GEL

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

Do not use Ibuprofen 5% Gel after the expiry date which is stated on the tube. The expiry date refers to the last day of that month. They 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 CONTENTS OF THE PACK AND OTHER INFORMATION

What Ibuprofen 5% Gel contains

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

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

Ibuprofen 5% Gel is supplied in aluminium tubes containing 30g or 50g of 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

Mercury Pharmaceuticals Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK.

Alternate Manufacturer

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Product Description	Generic Ibuprofen 5% Gel		
Component	Leaflet	HUB No.	8942
Component No.	4005098	Supplier	Mercury Pharma Ltd
Date	09/04/14	Supplier Code	TBC
Version	1	Cutter Profile	148x210mm
Amended By	DH	Pharmacode	TBC

Colour Swatches
 Black
 Cutter