

Package leaflet: information for the user
Nurofen Joint & Back Pain Relief 5% 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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If symptoms persist for more than 7 days, or worsen at any time, consult your doctor or pharmacist.
- 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 Nurofen Joint & Back Pain Relief 5% Gel is and what it is used for
2. What you need to know before you use Nurofen Joint & Back Pain Relief 5% Gel
3. How to use Nurofen Joint & Back Pain Relief 5% Gel
4. Possible side effects
5. How to store
6. Contents of the pack and other information

1. What Nurofen Joint & Back Pain Relief 5% Gel is and what it is used for

Nurofen Joint & Back Pain Relief 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.

Nurofen Joint & Back Pain Relief 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 Nurofen Joint & Back Pain Relief 5% Gel Do not use Nurofen Joint & Back Pain Relief 5% Gel:

- if you are allergic to ibuprofen, aspirin or any of the other ingredients of this medicine (see section 6)
- if you have had previous allergic reactions (e.g. asthma, runny nose, swelling, rash) when taking ibuprofen, aspirin or similar medicines
- if you are in the last three months of pregnancy- do not use on broken or damaged skin - in children under 12 years old.

Warnings and precautions

Do not let the product come into contact with the eyes, mouth or lips.

Take care when using this product to protect the treated area from sunlight exposure.

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.

Talk to your doctor or pharmacist before using Nurofen Joint & Back Pain Relief 5% Gel:

- if you are taking aspirin or any other pain-relieving medication
- if you are pregnant
- if you suffer from ulcers, or have problems with your stomach
- if you have asthma
- if you have liver or kidney problems.

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using this medicine and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Nurofen Joint & Back Pain Relief 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 blood pressure (e.g. atenolol)
- medicines used to thin the blood (e.g. warfarin)
- aspirin or other NSAIDs – used for inflammation and pain.

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 Nurofen Joint & Back Pain Relief 5% Gel if you are in the last 3 months of pregnancy.

You should not use Nurofen Joint & Back Pain Relief 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 Nurofen Joint & Back Pain Relief 5% Gel can cause adverse effects in your unborn baby. It is not known if the same risk applies to Nurofen Joint & Back Pain Relief 5% Gel when it is used on the skin.

Important information about some of the ingredients of Nurofen Joint & Back Pain Relief 5% Gel:

This medicine contains 1.25 mg benzyl alcohol in each dose. Benzyl alcohol may cause allergic reactions and mild local irritation.

3. How to use Nurofen Joint & Back Pain Relief 5% Gel

Always use this medicine as the leaflet tells you. Check with your doctor or pharmacist if you are unsure.

Check the seal is intact before first use. Invert cap to break seal. Nurofen Joint & Back Pain 5% Gel is for use on the skin only and should only be used on healthy, unbroken skin.

Do not

- use in the mouth or take it by mouth
- use near cuts and grazes or under dressings such as plasters
- use on the genital area
- let the gel come into contact with your eyes. If it does, rinse thoroughly and consult a doctor.

Wash your hands after applying the gel, unless they are the site of treatment.

Adults and children 12 years and over: Squeeze 4 to 10cm of gel from the tube and lightly rub onto 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.

Children under 12 years: Nurofen Joint & Back Pain 5% gel is not recommended for children under 12 years.

If symptoms persist for more than 7 days, or worsen at any time, consult your doctor or pharmacist. **If the gel is accidentally swallowed:** If you accidentally swallow any 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, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicine immediately and contact your doctor if any of the following occur:

- wheeziness, difficulty in breathing, swelling of the eyelids, face or lips or itching (especially affecting your whole body)
- severe skin reactions such as flaking, peeling or 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 may include:

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

- stomach pains
- kidney problems (particularly in people who have a history of kidney disease)
- reddening of the skin where the product is applied
- skin becomes sensitive to light

If any of these 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 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 Nurofen Joint & Back Pain Relief 5% Gel

Keep out of the sight and reach of children. Do not use Nurofen Joint & Back Pain Relief 5% Gel after the expiry date which is stated on the tube. Store 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.

6. Contents of the pack and other information

What Nurofen Joint & Back Pain Relief 5% Gel contains

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

What Nurofen Joint & Back Pain Relief 5% Gel looks like and contents of the pack

Nurofen Joint & Back Pain Relief 5% Gel is supplied in aluminium tubes containing 30g gel.

Marketing Authorisation Holder

Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 3UH

Manufacturer:

Reckitt Benckiser Healthcare (UK) Ltd, Hull, HU8 7DS.

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