

NUROFEN 5% W/W Gel

Ibuprofen

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Nurofen 5% w/w Gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- If any of the side-effects gets serious, or if you notice any side-effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nurofen 5% w/w Gel is and what it is used for
2. Before you use Nurofen 5% w/w Gel
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4. Possible side-effects
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6. Further Information

1. WHAT NUROFEN 5% W/W GEL IS AND WHAT IT IS USED FOR?

Nurofen 5% w/w Gel contains the active ingredient ibuprofen which belongs to a group of medicines known as non steroidal anti-inflammatory drugs (NSAIDs).

It is gently rubbed into the skin

- to relieve pain, reduce local heat, swelling and inflammation
- in conditions such as backache, rheumatic and muscular pain, sprains, strains and sports injuries.

2. BEFORE YOU USE NUROFEN 5% W/W GEL:

Do not use Nurofen 5% w/w Gel if you:

- are allergic to ibuprofen or any of the ingredients of Nurofen 5% w/w Gel listed in Section 6.
- are allergic to aspirin or other pain relievers known as non steroidal anti-inflammatory drugs (NSAIDs)
- have ever had an asthma attack, rash or runny nose after taking aspirin or any NSAIDs
- have broken or damaged skin
- are **under 12 years of age**
- are in the last 3 months of pregnancy

Consult your doctor or pharmacist before taking Nurofen 5% w/w Gel if you

- have asthma or have suffered from asthma
- are **taking aspirin, ibuprofen or other NSAID** pain relievers
- Are pregnant

Warnings and Precautions

One gram of gel contains 10mg of benzyl alcohol (1% w/w). Benzyl alcohol may cause mild local irritation.

Nurofen Gel is applied to the skin, there is less risk of the complications that sometimes occur when ibuprofen (or other NSAIDs) is taken by mouth. However, in rare cases you may be at risk:

- if you have a stomach ulcer (also called peptic or gastric ulcer)
- if you have kidney problems
- if you have liver problems
- if you have ever had asthma
- if you have ever had intestinal inflammation or hemorrhage

Take special care with Nurofen 5% Gel

- Use it only on the skin
- Keep the gel away from the eyes, nose and mouth
- Do not use it under waterproof dressings
- If you develop a rash after using the gel stop using it any further
- Protect treated areas from direct artificial or natural light to avoid any sensitivity reaction, e.g. a rash

Take special care with Nurofen 5% w/w Gel:

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using Nurofen 5% 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.

Taking other medicines

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting, e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol or angiotensin II receptor antagonists such as losartan) and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek the advice of a healthcare professional before you use ibuprofen with other medicines.

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 taking this medicine.

Do not use Nurofen 5% w/w Gel if you are in the last 3 months of pregnancy. You should not use Nurofen 5% 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 can cause adverse effects in your unborn baby. It is not known if the same risk applies to ibuprofen when it is used on the skin.

3. HOW TO USE NUROFEN 5%W/W GEL:

For cutaneous use (use on the skin) only. When first opening the tube, check that the tube seal is not broken. To break seal, press against the point hidden in the top surface of the cap.

Adults and children 12 years and over

Apply a thin layer (1.0g to 2.5g) of gel to the affected area and massage gently until absorbed. Leave four hours between doses and do not apply more than 4 times in any 24 hour period.

Maximum daily dose is 10g of gel which equates to 500mg of ibuprofen. Hands should be washed immediately after use. Do not exceed the stated dose.

Children under 12 years: Do not use on children under 12 years of age.

Do not

- Apply it more than 4 times in 24 hours.
- Use it on broken or inflamed skin, on the lips, genital area or near the eyes.
- Cover the area with bandages, dressings or plasters.

This gel is for **external use only**.

Length of treatment

If your symptoms worsen or if there is no improvement after 7 days treatment, talk to your doctor.

Stop using the gel if you develop a **rash** (see section 4).

If the gel is swallowed by mistake

If the gel is swallowed, rinse the mouth out with water. Swallowing the gel may cause an upset stomach. If you are concerned, talk to your doctor or pharmacist. If a child swallows the gel, talk to your doctor straight away.

4. POSSIBLE SIDE EFFECTS:

Like all medicines, Nurofen 5% w/w Gel can cause side-effects, although not everyone gets them.

Seek medical help at once if you develop any of the following rare reactions.

- Unexplained wheeziness, shortness of breath, onset of asthma, swelling of the face, lips or tongue, difficulty swallowing or breathing
- serious skin reactions such as itchy rashes, inflammation, swelling, peeling or cracking of the skin, raised red patches with blistering.
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the 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).
- Kidney problems such as swelling or decreased urine output.
- Skin becomes sensitivity to light (frequency unknown).

Tell your doctor if you are concerned about any of the following effects or have any other effects.

- mild reddening, tingling or itching where you have applied the gel
- stomach pain or indigestion.
- sudden constriction of the airways leading to difficulties breathing (particularly in people who have a history of asthma or allergic problems).

Reporting 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 HPRA Pharmacovigilance website: www.hpra.ie

5. HOWTO STORE NUROFEN 5% W/W GEL?

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Do not use after the expiry date printed on the carton and the tube. Do not store above 25°C.

6. FURTHER INFORMATION

What Nurofen 5% w/wGel contains

The active substance in Nurofen 5% w/w Gel is Ibuprofen 5% w/w. The other ingredients are purified water, isopropyl alcohol, hydroxyethylcellulose, benzyl alcohol, sodium hydroxide (E524).

What Nurofen 5%w/wGel looks like and contents of the pack

Nurofen 5% w/w Gel is a clear, colourless, smooth gel. It is available in a 30g or 50g tube. Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturers

PA Holder: Reckitt Benckiser Ireland Ltd, 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturers:

Farmasierra Manufacturing S.L., Ctra de Irún, Km 26,200, 28700 San Sebastian de los Reyes, Madrid, Spain.

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