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RB01501H

NUROFEN® EXPRESS 200mg TABLETS

Ibuprofen (as sodium ibuprofen dihydrate)

Package Leaflet: Information for the User

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

This medicine is available without prescription. However, you still need to take Nurofen Express 200mg Tablets 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 3 days.
- 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.

In this leaflet

1 What Nurofen Express 200mg Tablets are and what they are used for
2 Before you take Nurofen Express 200mg Tablets
3 How to take Nurofen Express 200mg Tablets
4 Possible side effects
5 How to store Nurofen Express 200mg Tablets
6 Further information

1. What Nurofen Express 200mg Tablets are and what they are used for:

The active ingredient (which makes the medicine work) in Nurofen Express 200mg Tablets is ibuprofen 200 mg (as sodium ibuprofen dihydrate 256mg). Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines work by changing how the body responds to pain, swelling and high temperature.

Nurofen Express 200mg Tablets are used for the relief of fever and mild to moderate pain such as:

- headaches, period pain, and dental pain
- muscle pain and backache
- symptoms of colds and flu, and high temperature (fever)

2. Before you take Nurofen Express 200mg Tablets

Do not take these tablets if you:

- are allergic (hypersensitive) to ibuprofen or any of the other ingredients (see Section 6: Further Information)
- are allergic (hypersensitive) to aspirin or to other painkillers
- have or ever had a stomach ulcer, perforation or bleeding in the stomach
- have ever had gastrointestinal bleeding in relation to NSAID therapy
- have severe liver or kidney problems
- have heart problems, high or low blood pressure or blood coagulation disorder
- have difficulties breathing or have had a worsening of asthma, skin rash, itchy runny nose, or facial swelling when previously taken ibuprofen, aspirin or similar medicines
- If you are taking other regular medication, other NSAID's or pain killers
- If you have been told by your doctor that you have an intolerance to some sugars (e.g. fructose)
- If you are pregnant or elderly
- If you are under 12 years of age

Speak to your doctor or pharmacist before taking these tablets if you:

- have uncontrolled high blood pressure any heart problems, any disease of the arteries or blood vessels
- are taking painkiller medication and find that you still have frequent or daily headaches despite taking medication please speak to your doctor
- have high or low blood pressure
- have or ever have had asthma
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously had heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, crohn's disease)
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pain, skin changes and problems with other parts of your body
- have been told to limit the amount of sodium in your diet
- are elderly

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular, do NOT take this product if you are taking any of the following:

- aspirin or other NSAIDs (e.g. COX-2 inhibitors such as celecoxib or etoricoxib).
- medicines for thinning the blood/prevent clotting (e.g. aspirin/acetylsalicylic acid, warfarin or ticlopidine).
- medicines that reduce high blood pressure (ACE inhibitors such as captopril, beta-blockers such as atenolol or angiotensin II receptor antagonists such as losartan)

Avoid taking this product with corticosteroid tablets, quinolone antibiotics, aminoglycoides, anti-hypertensives, mifepristone, probenecid, oral hypoglycaemic agents or drugs that are prescribed to:

- to stimulate your heart (e.g. glycosides) or to treat high blood pressure
- to help you passing water (diuretics)
- treat cancer, rheumatism or to temporarily suppress your immune system (e.g. methotrexate, cyclosporine, tacrolimus)
- for mania or depression (e.g. lithium , SSRI's)
- for HIV treatment (e.g. zidovudine)

You should therefore always seek your doctors or pharmacists advice before taking ibuprofen with any other medicines.

Other Warnings

- Nurofen Express 200mg Tablets belongs to a group of medicines which may impair fertility in women. This is reversible upon stopping the medicine. It is unlikely that using this medicine occasionally will affect your chances of becoming pregnant. However, talk to your doctor before taking ibuprofen if you have problems becoming pregnant.
- Medicines such as Nurofen Express 200mg Tablets may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged use. Do not exceed the recommended dose or duration of treatment.
- If you have heart problems, history of previous stroke or think you may be at risk of these conditions (for example if you have high blood pressure, diabetes, or high cholesterol) your should discuss treatment with your doctor.

There is a risk of renal impairment in dehydrated adolescents.

Pregnancy and breast-feeding

Do not take this medicine in the last 3 months of pregnancy. Avoid the use of this medicine in the first 6 months of pregnancy, unless advised by your doctor.

Ibuprofen can pass in very small concentrations into the breast milk. Speak to your doctor or pharmacist before taking this medicine if you are breast-feeding.

Ibuprofen belongs to a group of medicines which may reduce fertility in women. Fertility will go back to normal when you stop taking the medicine (see Other Warnings).

Important information about some of the ingredients

Each tablet contains an average of 24.6mg (1.07mmol) of sodium. This should be taken into consideration for people on a sodium controlled diet. Each tablet contains 93.1mg of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take Nurofen Express 200mg Tablets

This product is for short term use only. You should take the lowest dose for the shortest time necessary to relieve your symptoms. If your symptoms do not improve within 3 days consult your doctor.

Adults, the Elderly and children over 12 years old:

Take the tablets by mouth only with a glass of water.

- Take 1 or 2 tablets with a glass of water up to 3 times a day if required. Leave at least 4 hours between doses and do not take more than 6 tablets in 24 hours.

Do not give these tablets to children under 12 years.
This medicine is for short-term use only.

If in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

If your symptoms persist or the pain worsens, or any new symptoms occur, consult your doctor or pharmacist.

If you take more tablets than you should, you may feel drowsy or nauseous. You should seek immediate medical advice in the event of an over dose even if you feel well.

If you forget to take Nurofen Express 200mg Tablets: Simply refer to the direction above on how to take the medicine and do not take more than is advised.

4. Possible Side Effects

Like all medicines, ibuprofen can cause side effects, although not everybody gets them. Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. Nurofen Express 200mg Tablets are generally well tolerated by most people. However side effects may occur.

STOP TAKING this medicine and seek immediate medical attention if you develop:

- **signs of intestinal bleeding.** Such as bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee granules. Intestinal bleeding may occur more often in the elderly. In very rare cases this may be fatal.
- **signs of serious allergic reaction** such as:
  - difficulties breathing or unexplained wheezing
  - dizziness or faster heartbeat
  - severe skins reaction (skin lesions, rashes, itchiness...)
  - swelling of your tongue, face or throat.
  - Stevens Johnsons Syndrome (SJS) and Toxic Epidermal Necrolysis may occur very rarely. Which is a hypersensitivity reaction affecting the mucous membranes of the skin.
- **signs of aseptic meningitis** such as: stiff neck, headache, dizziness, feeling sick, being sick, fever or consciousness. Patients with auto-immune disorders (lupus, mixed connective tissue disease) may be more likely to be affected.

Tell your doctor if you experience:

- fever, flu-like symptoms, sore throat, mouth ulcers, vomiting, unexplained bleeding and bruising, severe exhaustion, nose or skin bleeding. This may be a symptom of a blood or lymphatic disorder.
- skin reactions, such as redness, rashes, itchiness, or formation of skin lesions. Worsening of asthma or bronchospasm.
- Hearing problems
- indigestion, stomach pain, constipation, diarrhoea, flatulence or if you feel sick (vomiting).
- Peptic ulcers, exacerbation of colitis and Crohn's disease.
- chest pain, drop in blood pressure or fast irregular heart beat.
- liver and kidney problems associated with swelling, decreased urine out put and very rarely renal failure associated with long term use.

Medicines such as Nurofen Express 200mg Tablets may be associated with a small increased risk of heart attack ('myocardial infraction') or stroke. See section 2 Other Warnings.

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

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, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +3533 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store Nurofen Express 200mg Tablets

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

This medicinal product does not require any special storage precautions. Do not use this medicine after the expiry date stated on the outer carton and blister pack. The expiry date refers to the last day of that month.

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

6. Further Information

What Nurofen Express 200mg Tablets contain:
The active ingredient is ibuprofen 200mg (as sodium ibuprofen dihydrate 256mg). Other ingredients are: Croscarmellose sodium (E468), magnesium stearate (E572), xylitol (E967), sucrose, titanium dioxide (E171), microcrystalline cellulose (E460), colloidal anhydrous silica (E551),carmellose sodium (E466), talc (E553b), acacia spray dried (E414), macrogol 6000 powder, Opacode Black ink containing: Shellac E904, Iron oxide black E172 and propylene glycol.

What Nurofen Express 200mg Tablets look like and contents of the pack

The tablets are round in shape and white in colour. Tablets are available in packs of 12, 24 and 48. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Manufactured by: Reckitt Benckiser Healthcare International, 1 Thane Road West, Nottingham, NG90 2DB, United Kingdom.

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For product queries please telephone: (01) 6305429

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