

## Package Leaflet: Information for the User

### NUROFEN Express Maximum Strength 400 mg Tablets

ibuprofen (as sodium dihydrate)

#### 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 Maximum Strength 400 mg 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.

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#### 1. What Nurofen Express Maximum Strength 400 mg Tablets are and what are they used for:

The active ingredient (which makes the medicine work) in Nurofen Express Maximum Strength 400 mg Tablets is ibuprofen 400 mg (as sodium dihydrate 512mg). 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 Maximum Strength 400 mg 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 Maximum Strength 400 mg 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 severe heart failure
- 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 an infection – please see heading 'Infections' below
- have uncontrolled high blood pressure any heart problems, any disease of the arteries or blood vessels
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- are taking painkiller medication and find that you still have frequent or daily headaches despite taking medication please speak to your doctor
- have low blood pressure
- have or ever have had asthma
- have kidney, liver or bowel problems
- have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including "mini-stroke" or transient ischaemic attack "TIA")
- 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
- have chicken pox as it is advisable to avoid the use of Nurofen Express Maximum Strength 400 mg Tablets.

Signs of an allergic reaction to this medicine including breathing problems, swelling of the face and neck region (angioedema) and chest pain have

been reported with ibuprofen. Stop taking Nurofen Express Maximum Strength 400 mg Tablets immediately and contact your doctor or medical emergencies if you notice any of these signs.

#### Take special care with Nurofen Express Maximum Strength 400 mg Tablets:

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 Express Maximum Strength 400mg Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in Section 4.

Infections: Nurofen Express Maximum Strength 400 mg Tablets may hide signs of infections such as fever and pain. It is therefore possible that Nurofen Express Maximum Strength 400 mg Tablets may delay appropriate treatment of infection which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chicken pox. If you take this medicine while you have an infection and the symptoms of the infection persist or worsen, consult a doctor without delay.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. In particular, discuss with your doctor or pharmacist if you are taking any of the following:

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

Avoid taking this product with corticosteroid tablets, quinolone antibiotics, aminoglycosides, 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)

**Some other medicines may also affect or be affected by the treatment of Nurofen Express Maximum Strength 400 mg Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen Express Maximum Strength 400 mg Tablets with other medicines.**

#### Other Warnings

Nurofen Express Maximum Strength 400 mg 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.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

There is a risk of renal impairment in dehydrated adolescents.

#### Pregnancy and breast-feeding

Do not take if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn child. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You should not take during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor.

If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used.

If taken for more than a few days from 20 weeks of pregnancy onward, it can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

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 sodium. This should be taken into consideration for people on a sodium controlled diet. Each tablet contains 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 Maximum Strength 400 mg Tablets

This product is for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see Section 2). 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 ONLY 1 TABLET 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 3 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:

If you have taken more Nurofen Express Maximum Strength 400 mg Tablets than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advise on action to be taken. The symptoms of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in the blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to the interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

#### If you forget to take Nurofen Express Maximum Strength 400 mg

**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 Maximum Strength 400 mg 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 skin reaction (skin lesions, rashes, itchiness...)
  - swelling of your tongue, face or throat.
  - 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)
- **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 which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- drop in blood pressure or fast irregular heart beat.
- liver and kidney problems associated with swelling, decreased urine output and very rarely renal failure associated with long term use.
- severe skin infections and soft tissue complications during chicken pox (varicella) infection.
- Skin becomes sensitive to light.

Medicines such as Nurofen Express Maximum Strength 400 mg Tablets may be associated with a small increased risk of heart attack ('myocardial infarction') 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie)

### 5. How to Store Nurofen Express Maximum Strength 400 mg Tablets

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month. 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 protect the environment.

### 6. Further Information

#### What Nurofen Express Maximum Strength 400 mg Tablets contain:

The active ingredient is ibuprofen 400 mg (as sodium dihydrate). 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 gum (E414), macrogol 6000, red printing ink containing shellac, iron oxide red (E172), propylene glycol (E1520), ammonium hydroxide (E527) and simethicone.

#### What Nurofen Express Maximum Strength 400 mg Tablets look like and contents of the pack

The tablets are round in shape and white in colour with an identifying logo in red on one face. Tablets are available in packs of 12, and 24.

#### Parallel Product Authorisation Holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

#### Manufactured by

RB NL Brands B.V., Schiphol Boulevard 207, 1118 BH Schiphol, The Netherlands.

#### Repackaged by

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