PACKAGE LEAFLET: INFORMATION FOR THE USER

Nurofen® Advance Maximum Strength 400mg Oral Powder
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 take Nurofen® Advance 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 in children and adolescents
- after 5 days when treating pain or 3 days when treating fever in adults.
- 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® ADVANCE IS AND WHAT IT IS USED FOR

Nurofen® Advance contains ibuprofen 400mg as ibuprofen lysinate. Ibuprofen belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These medicines provide relief by changing the body's response to pain, swelling and high temperature.

Nurofen® Advance is used to relieve:

- symptoms of mild to moderate pain such as headache, toothache, period pains, rheumatic and muscular pain and migraine.
- cold and flu symptoms such as sore throat and fever.

2. BEFORE YOU TAKE NUROFEN® ADVANCE

Do not take Nurofen® Advance if you:

- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding of the stomach
- are allergic to ibuprofen, tartrazine (E102) or any of the other ingredients (see section 6) of Nurofen Advance or to acetylsalicylic acid (aspirin) or other anti-inflammatory painkillers
- suffer from severe kidney, liver or heart problems

- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (Non-Steroidal Anti-inflammatory drugs)
- have ever suffered from shortness of breath, have had asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, acetylsalicylic acid (aspirin) or other similar painkillers (NSAIDs)
- are suffering from severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake)
- are suffering from cerebrovascular or other active bleeding
- are suffering from blood cell production or clotting disorders
- are in the last three months of pregnancy (see below).

Please do not give to children under 12 years of age.

Speak to a pharmacist or your doctor before taking this product if you:

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have been told by your doctor that you have an intolerance to some sugars
- have systemic lupus erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- have a history of gastrointestinal disease (such as ulcerative colitis or Crohn's disease)
- are in the first 6 months of pregnancy
- have chicken pox (varicella).

Consult a doctor before using Nurofen® Advance if any above mentioned conditions concerns you.

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.

You should discuss your treatment with your doctor or pharmacist before taking Nurofen® Advance if you:

- 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 arterties), or any kind of stroke (including "mini-stroke" or transient ischaemic attack "TIA").
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell them if you are taking:

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- glucocorticoids (medicinal products containing cortisone or cortisone-like substances), aspirin, or other NSAIDs (anti-inflammatories and analgesics): since these may increase the risk of gastrointestinal ulcers or bleeding
- lithium (a medicine for manic depressive illness and depression) since the effect of lithium may be enhanced
- selective serotonin reuptake inhibitors (a medicine used for depression) as these may increase the risk of gastrointestinal side effects.
- methotrexate (a medicine for cancer or rheumatism) since the effect of methotrexate may be enhanced
- zidovudine: (a medicine for treating HIV infection) since the use of Nurofen Advance may result in an increased risk of bleeding into a joint or a bleeding that leads to swelling.
- ciclosporin and tacrolimus (to prevent transplant rejection) as there could be an increased risk for the kidney.
- water tablets (diuretics), as NSAIDs may reduce the effects of these medicines and there could be a possible increased risk for the kidney (using potassium sparing diuretics with ibuprofen can lead to high blood levels of potassium)
- sulfonylureas (antidiabetic medicine) as interactions may be possible
- phenytoin (for epilepsy) as the effect may be enhanced
- quinolone antibiotics as the risk of convulsions may be increased.
- cardiac glycosides such as digoxin
- mifepristone (used to terminate pregnancies) as the effect may be reduced
- probenecid and sulfinpyrazones (medicines for gout): it may take longer for ibuprofen to be broken down by the body.

Nurofen® Advance may affect or be affected by some other medicines. For example:

- 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)

Some other medicines may also affect or be affected by the treatment of Nurofen® Advance. You should therefore always seek the advice of your doctor or pharmacist before you use Nurofen® Advance with other medicines.

Other warnings

- Taking a painkiller for headaches for too long can make them worse.
- There is a risk of renal impairment in dehydrated children and adolescents.

Fertility, pregnancy and breast-feeding

Do not take in the last 3 months of pregnancy. Speak to your doctor or pharmacist before taking this product if you are in the first 6 months of pregnancy or are breast-feeding.

This medicine passes into breast milk but may be used during breast-feeding if it is used at the recommended dose and for the shortest possible time.

Nurofen Advance belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that Nurofen Advance, used occasionally will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines
For short-term use and at normal dosage this medicine has no or negligible influence on the ability to drive and use machines. If side-effects such as tiredness or dizziness occur do not drive or operate machines. Alcohol consumption increases the risk of these side-effect.

Important information about some of the ingredients of Nurofen® Advance .
Nurofen Advance contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Nurofen Advance contains tartrazine (E102). This may cause allergic reactions.

3. HOW TO TAKE NUROFEN® ADVANCE
This product is for **short term use** only. You should take the lowest dose for the shortest time necessary to relieve your symptoms.
Always take Nurofen® Advance Oral Powder exactly as stated in this package leaflet. You should check with your doctor or pharmacist if you are not sure. The standard dose is:

Adults and children aged 12 years and older:
For oral use after dissolving in water.
Dissolve the content of one sachet in a glass of water, stir and then drink immediately.
You can take one sachet up to three times a day as required.
Leave at least six hours between doses.
Do not take more than three sachets in any 24 hour period.
Not to be given to children under 12 years of age

In children and adolescents

If in children and adolescents between 12 and 18 years Nurofen Advance is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

In adults

You should not take Nurofen Advance for longer than 5 days when treating pain and 3 days when treating fever unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

Please speak to the doctor or pharmacist if you feel that the effect of this medicine is greater or less than you expected.

If you take more Nurofen® Advance than you should
Consult a doctor immediately. The following signs may occur: nausea, vomiting, stomach pain, headache, dizziness, drowsiness, nystagmus, blurred vision, ringing in the ear. Rarely: low blood pressure and loss of consciousness.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nurofen Advance 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. Although side effects are uncommon, you may suffer one of the known side effects of NSAIDs. If you do, or if you have concerns, stop taking this medicine and talk to your doctor as soon as possible. Elderly people using this product are at increased risk of developing problems associated with side effects.

The following frequencies are taken as a basis when evaluating side effects:

very common: affects more than 1 user in 10
common: affects 1 to 10 users in 100
uncommon: affects 1 to 10 users in 1,000
rare: affects 1 to 10 users in 10,000
very rare: affects less than 1 user in 10,000
not known: frequency cannot be estimated from the available data

STOP TAKING this medicine and seek immediate medical help if you develop:
- **signs of intestinal bleeding** such as: severe pain in the abdomen, black tarry stools, blood in your faeces (stools/motions), vomiting blood or dark particles that look like coffee grounds.
- **signs of very rare but serious allergic reaction** such as worsening of asthma, unexplained wheezing or shortness of breath, swelling of the face, tongue or throat, difficulty breathing, racing heart, drop in blood pressure leading to shock. These can happen even on first use of this medicine.
- **severe skin reactions** such as rashes covering the whole body, peeling, blistering or flaking skin.

Tell your doctor if you have any of the following side effects, they become worse or you notice any effects not listed.

Common
- heart burn, abdominal pain, feeling sick and indigestion,

Uncommon
- inflammation of the stomach, worsening of colitis and Crohn's disease
- headache, dizziness, sleeplessness, agitation, irritability or tiredness
- visual disturbances
- flatulence (wind), diarrhoea, constipation and vomiting
- allergic reactions , such as skin rashes, itching and asthma attacks

Rare
- tinnitus (ringing in the ears)
- kidney damage and the development of gout

Very rare
- inflammation of the oesophagus or pancreas, blockages in the gut
- serious infections of the skin have occurred during chicken pox.
- kidney disorders that may be shown by passing less or more urine than normal, cloudy urine, blood in the urine, pain in the back and/or swelling (particularly of the legs). In general, the habitual use of (several sorts of) analgesics can lead in rare cases to lasting severe kidney problems.
- blood disorders resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion.
- psychotic reactions and depression
- worsening of inflammation due to infection.
- high blood pressure, arterial hypertension, palpitations, heart failure, heart attack.
- liver problems or inflammation of the liver. Liver failure or damage, particularly in long-term term use, shown by yellowing of the skin and eyes or pale stools and dark urine.
- the symptoms of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness clouding have been observed when using ibuprofen. Patients with autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected. Contact a doctor at once, if these occur.
- swelling of skin tissue such as hands, feet or face.

Medicines such as Nurofen Advance may be associated with a small increased risk of heart attack (''myocardial infarction'') or stroke.

Reporting of 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, Earlsfort Terrace, IRL-

Dublin 2. Tel: +353 1 6764971. Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

5. HOW TO STORE NUROFEN® ADVANCE

Keep out of the reach and sight of children.

This medicinal product does not require any special temperature storage conditions.

Do not use Nurofen® Advance after the expiry date which is stated on the carton and sachets. The expiry date refers to the last day of that month.

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

6. FURTHER INFORMATION

What Nurofen® Advance contains: Each sachet contains 400mg of the active substance ibuprofen (as ibuprofen lysinate).

The other ingredients are:
Betadex
Lemon essence (containing natural flavouring substances and preparations, maltodextrin, modified maize starch and tartrazine E102)
Sodium saccharin (E954)
Sodium cyclamate (E952)
Sodium citrate (E331)
Sucrose

What Nurofen® Advance looks like and contents of the pack:
This medicine is a white, lemon flavoured powder supplied in single dose sachets.
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Outer carton containing 2, 3, 4, 5, 6, 8, 10, 12, 13, 14, 15 and 16 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturer
Laboratorio de aplicaciones farmacodinámicas, s.a. (fardi)
Grassot, 16
08025 BARCELONA (SPAIN)

Or

Reckitt Benckiser Healthcare International Limited
Thane Road, Nottingham,
NG90 2DB, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Nurofen Instant 400mg rozpustny prášek
Hungary	Nurofen Rapid Forte por belsőleges oldathoz
Netherlands	Nurofen Zavance 40 mg, poeder voor oraal gebruik
Poland	Nurofen Ultra Forte rozpuszczalny
Romania	Nurofen Express 400 mg pulbere orals
Slovakia	Nurofen Instant 400mg perorální prášek
United Kingdom	Nurofen Express Soluble 400mg oral powder

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