**Essential Information**: **Nurofen Express 400 mg Liquid Capsules PL 00063/0653**

**Active Ingredient (s)**: Each capsule, soft contains Ibuprofen 400 mg.

**Indications**: for symptomatic relief of non-serious arthritic conditions, rheumatic or muscular pain, backache, neuralgia, migraine, headaches, dental pain, dysmenorrhoea, feverishness, colds and influenza.

**Dosage & Administration**:
*Posology:* The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4). Adults, the elderly and children and adolescents between 12 and 18 years: Take 1 capsule with water, up to three times a day as required. Leave at least 4 hours between doses. Do not take more than 3 capsules in any 24 hour period. Not for use by children under 12 years of age. If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted. Adults should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.
*Method of Administration:* For oral administration and short-term use only.

**Contraindications**: Known hypersensitivity to ibuprofen or other ingredients. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioderma or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs.
Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. Severe heart failure (NYHA Class IV), renal failure or hepatic failure. Last trimester of pregnancy.

**Special warnings and precautions for use**: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal. Respiratory: Bronchospasm may be precipitated in patients suffering from, or with a history of, bronchial asthma or allergic disease. Other NSAIDs: The use of ibuprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. SLE and mixed connective tissue disease: Systemic lupus erythematosus as well as those with mixed connective tissue disease – increased risk of aseptic meningitis. Renal: Renal impairment as renal function may further deteriorate. There is a risk of renal impairment in dehydrated children and adolescents. Hepatic: Hepatic dysfunction. Cardiovascular and cerebrovascular effects. Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy. Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200mg/day) is associated with an increased risk of arterial thrombotic events. Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided. Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, and smoking), particularly if high doses of ibuprofen (2400 mg/day) are required. Impaired female fertility: There is limited evidence that drugs which inhibit cyclooxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment. Gastrointestinal: NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated. GI bleeding,

ulceration or perforation, which can be fatal has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of GI events. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available. Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or antiplatelet agents such as aspirin. When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn. Dermatological: Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Ibuprofen should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. This medicine contains 27.9 mg potassium per capsule. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.
Contains Sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Also contains Ponceau 4R (E124) which may cause allergic reactions.

Severe skin reactions

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported rarely in association with the use of NSAIDs (see section 4.8). Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Ibuprofen should be discontinued at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

Masking of symptoms of underlying infections

This medicinal product can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine is administered for pain or fever in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

**Fertility, Pregnancy and Lactation:**

*Pregnancy:*

During the first and second trimester of pregnancy, Nurofen should not be given unless clearly necessary. If Nurofen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to: cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension); renal dysfunction, which may progress to renal failure with oligohydroamniosis; the mother and the neonate, at the end of the pregnancy, to: possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses; inhibition of uterine contractions resulting in delayed or prolonged labour.
Consequently, Nurofen is contraindicated during the third trimester of pregnancy.

*Lactation:*

In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely.

**Side effects**:

| System Organ Class | Frequency | Adverse Event |
|---|---|---|
| Blood and Lymphatic System Disorders | Very rare: | Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising. |
| Immune System Disorders | | Hypersensitivity reactions consisting of[1]: |
| | Uncommon | Urticaria and pruritus |
| | Very rare | Severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock). |
| | Not Known | Respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea. |
| Nervous System Disorders | Uncommon | Headache |
| | Very rare | Aseptic meningitis[2] |
| Cardiac Disorders | Not Known | Cardiac failure and oedema |
| Vascular Disorders | Not Known | Hypertension |
| Gastrointestinal Disorders | Uncommon | Abdominal pain, nausea, dyspepsia |
| | Rare | Diarrhoea, flatulence, constipation and vomiting |
| | Very rare | Peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis |
| | Not Known | Exacerbation of colitis and Crohn's disease (section 4.4). |
| Hepatobiliary Disorders | Very rare | Liver disorders |
| Skin and Subcutaneous Tissue Disorders | Uncommon | Various skin rashes |
| | Very rare | Severe forms of skin reactions such as bullous reactions including |

| | | |
|---|---|---|
| | Not known | Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur.<br><br>Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)<br>Acute generalised exanthematous pustulosis (AGEP)<br>Photosensitivity reactions |
| Renal and Urinary Disorders | Very rare<br><br>Not Known | Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.<br><br>Renal insufficiency |
| Investigations | Very rare | Decreased haemoglobin levels |

**Legal Classification:** P

**Licence Holder**: Reckitt Benckiser Healthcare (UK) Ltd, SL1 4AQ

**License Number**: PL 00063/0653

**Price (ex VAT): MRRP** £ 9.99 (20 capsules)

**Last Revised**: 08/01/2021

**Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) Ltd on: 0333 200 5345**