

Nurofen Express 400 mg Liquid Capsules: 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 and Administration:** 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.

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. $\leq 1200\text{mg/day}$) 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. **Side effects:** Hypersensitivity reactions including: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea, (c) various skin reactions e.g. pruritus, urticaria, purpura, angioedema and more rarely exfoliative, bullous dermatoses (including epidermal necrolysis and erythema multiforme) and DRESS syndrome (drug reaction with eosinophilia and systemic symptoms). Gastrointestinal disturbance including: peptic ulcer, perforation or GI haemorrhage, headache, acute renal failure, liver disorders, and haematopoietic disorders including anaemia. **Product Licence Number:** PL 00063/0653. **Licence Holder:** Reckitt Benckiser Healthcare (UK) Ltd, SL1 4AQ. **Legal category:** P **MRRP:** £ 9.99 (20 capsules) **Date:** June 2018 – For full information refer to SPC: <http://www.medicines.org.uk/emc/medicine/23384>

Reporting of Suspected Adverse Reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.