1.5mm

NUROFEN EXPRESS 684mg CAPLET

Ibuprofen Lysine 684mg

Product Description
Film-coated, white, capsule-shaped tablet, printed with an indentifying logo in black on one face. Also contains: Povidone, sodium starch glycollate Type A, magnesium stearate, hypromellose, talc, Opaspray White M-1-7111B (contains hypromellose and titanium dioxide (E171)) and Black Printing Ink (contains shellac, Iron oxide black (E172) and propylene glycol).
Pharmacodynamics
Ibuprofen lysine is the lysine salt of ibuprofen, a propionic acid derivative, having analgesic, anti-inflammatory and antipyretic activity. The therapeutic effects of ibuprofen lysine as a non steroidal anti-inflammatory drug are thought to result from inhibitory activity on prostaglandin synthesis.
Following oral administration, ibuprofen lysine dissociates to ibuprofen acid and lysine. Lysine has no recognized pharmacological activity. The pharmacological properties of ibuprofen lysine, therefore, are the same as those of ibuprofen acid. Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 hours before or within 30 minutes after immediate release aspirin dosing (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no relevant effect is considered to be likely for occasional ibuprofen use.
Pharmacokinetics
Most pharmacokinetic data obtained following the administration of ibuprofen acid also apply to ibuprofen lysine. Peak plasma concentrations occur 1-2 hours after administration of ibuprofen acid. However, ibuprofen is more rapidly absorbed from the gastrointestinal tract following the administration of Nurofen Express 684mg Caplet, with peak plasma concentrations occurring approximately 35 minutes after administration in the fasting state.
The elimination half-life of ibuprofen acid is approximately 2 hours.
The drug is extensively bound to plasma proteins.
Ibuprofen is metabolized in the liver to two inactive metabolites and these, together with unchanged ibuprofen, are excreted by the kidney either as such or as conjugates. Excretion by the kidney is both rapid and complete. No specific difference in pharmacokinetic profile is observed in the elderly.
Indications
Nurofen Express is indicated for the relief of pain such as headache, migraine pain, dental pain, period pain, rheumatic pain, muscular pain and backache. It also relieves fever such as fever associated with cold & flu.
Recommended Dose
For oral administration and short-term use only.
Adults, the elderly and children over 12 years:
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.
Take 1 caplet with water, up to three times a day as required. Leave at least 4 hours between doses.
Do not take more than 3 caplets in any 24 hour period.
Route of administration
Oral
Contraindications
Hypersensitivity to ibuprofen or any of the excipients in the product.
Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, 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, renal failure or hepatic failure (see Special warning and precaution for use)
Last trimester of pregnancy (see Pregnancy and lactation)
In patients who have recently undergone coronary artery bypass graft (CABG) surgery and revascularization procedures.
Warnings and precautions
Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).
The elderly have an increased frequency of adverse reaction to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.
Respiratory: Bronchospasm may be precipitated in patients suffering from, or with a previous history of bronchial asthma or allergic disease.
Other NSAIDs: The use of ibuprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see Interaction with other medicinal products and other forms of interaction)
SLE and mixed connective tissue disease: Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis (see Side effects).
Renal: Renal impairment as renal function may further deteriorate (see Contraindications and Side effects).
Hepatic: Hepatic dysfunction (see Contraindications and Side effects).
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 trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400mg daily) and in long-term treatment may be associated with a small increased in risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen e.g. ≤1200mg daily) is associated with an increased risk of myocardial infarction.
Impaired female fertility: There is limited evidence that drugs which inhibit cyclo-oxygenase/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, Chrohn's disease) as these conditions may be exacerbated (see Side effects).
GI bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime 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 (see Contraindications), 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 anti-platelet agents such as aspirin (see Interaction with other medicinal products and other forms of interactions).
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 (see Side Effects). Patients appear to be at highest risk for 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 sign of hypersensitivity.
Interaction with other medicinal products and other forms of interactions
The following drug interactions have been identified for ibuprofen acid:
Ibuprofen (like other NSAIDs) should be avoided in combination with:
Aspirin: unless low-dose aspirin (not above 75mg daily) has been advised by a doctor as this may increase the risk of adverse reactions (see Warnings and precautions).
Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see Pharmacodynamic properties)
Other NSAIDs including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse effects (see Warnings and precautions).
Ibuprofen should be used with caution in combination with:
Corticosteroids: as these may increase the risk of gastrointestinal ulceration or bleeding (see Warnings and precautions).
Date of Revision: Aug 2021

NUROFEN EXPRESS 684mg CAPLET

Ibuprofen Lysine 684mg

Antihypertensives and diuretics: since NSAIDs may diminish the effects of these drugs. Diuretics can increase the risk of nephrotoxocity of NSAIDs.
Anticoagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see Warnings and Precautions).
Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see Warnings and Precautions).
Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.
Lithium: There is evidence for the potential increase in plasma levels of lithium
Methotrexate: There is evidence for the potential increase in plasma levels of methotrexate.
Ciclosporin: Increased risk of nephrotoxicity.
Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.
Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
Pregnancy and lactation
No specific studies have been conducted with ibuprofen lysine.
Whilst no teratogenic effects have been demonstrated with ibuprofen acid in animal experiments, the use of ibuprofen during pregnancy should, if possible, be avoided during the first 6 months of pregnancy. It should not be used for the last trimester of pregnancy as there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and duration increased, with an increased bleeding tendency in both mother and child. (See Contraindications). In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely (see Warnings and Precautions regarding female fertility).
Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.
Effects on ability to drive and use machines
None expected at recommended dose and duration of therapy.
Side effects
Hypersensitivity reactions have been reported and these may consist of: (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnea, or (c) various skin reactions e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).
Hypersensitivity reactions: Uncommon: Hypersensitivity reactions with urticaria and pruritis.
Very rare: severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dysponoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock).
Exacerbation of asthma and bronchospasm.
Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature.
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.
Exacerbation of colitis and Crohn's disease (see Warnings and precautions).
Nervous System: Uncommon: Headache
Very rare: Aseptic meningitis – single cases have been reported very rarely.
Renal: Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.
Hepatic: Very rare: liver disorders.
Haematological: 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.
Dermatological: Uncommon: Various skin rashes
Very rare: Severe forms of skin reactions such as bullous reactions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur.
Immune System: In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (see Warnings and precautions).
Cardiovascular and Cerebrovascular: Oedema, hypertension and cardiac failure, have been reported in association with NSAID treatment.
Clinical trial and epidemiological data suggest that the use of NSAIDS (particularly at high doses 2400mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see Warnings and precautions).
Symptoms and treatment of overdose
In children ingestion of more than 400mg/kg may cause symptoms. In adults the dose response effect is less clear cut.
The half-life in overdose is 1.5 – 3 hours.
Symptoms: Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients may develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time / INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.
Management: Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.
List of excipients
Povidone, sodium starch glycolate, magnesium stearate, hypromellose, talc, Opaspray White M-1-7111B (contains hypromellose and titanium dioxide (E171)) and Black Printing Ink (contains shellac, Iron oxide black (E172) and propylene glycol).
Storage conditions
Do not store above 30°C. Store in the original container.
Shelf life
24 months
Nature and contents of container
A blister pack consisting of opaque, white 250µm polyvinyl chloride (PVC)/120gm² polyvinylidene chloride (PVdC) laminate heat sealed to 20µm aluminium foil. The blisters are packed in cardboard cartons.
Pack size
A box of 12 caplets
Manufactured by: Reckitt Benckiser Healthcare International Limited
Thane Road, Nottingham, Nottinghamshire, NG90 2DB, United Kingdom.
License Holder & Importer:
Reckitt Benckiser (Singapore) Pte. Ltd.
12 Marina Boulevard #19 – 01, Marina Bay Financial Centre, Tower 3, Singapore 018982
RB (Health) Malaysia Sdn. Bhd (1297081-V)
Level 17, Menara One Sentrum, No.201, Jalan Tun Sambathan, 50470 Kuala Lumpur, Malaysia
Date of Revision: Aug 2021