

NUROFEN[®]

TABLETS

LIQUID CAPSULES

NUROFEN[®] FORTE

TABLETS

NUROFEN[®] FOR CHILDREN

SUSPENSION

Composition

Nurofen Tablets

Each tablet contains:

Active Ingredient

Ibuprofen 200 mg

Other Ingredients

Sucrose*, sodium citrate, calcium sulfate dihydrate, croscarmellose sodium, stearic acid, titanium dioxide, colloidal anhydrous silica, carmellose sodium, acacia spray dried, sodium laurilsulfate, carnauba wax powder, shellac, iron oxide black (E172), soya lecithin, antifoam DC 1510.

* Sugar content: 113 mg/tablet.

Nurofen Liquid Capsules

Active Ingredient

Ibuprofen 200 mg

Other Ingredients

Polyethylene glycol 600, povidone, vitamin E polyethylene glycol succinate [USNF], gelatin, maltitol liquid, sorbitol special solution, purified water, Ponceau 4R (E 124), titanium dioxide, shellac, soya lecithin.

Sorbitol content::11 mg – 16.4 mg per liquid capsule.

Nurofen Forte Tablets

Active Ingredient

Ibuprofen 400 mg

Other Ingredients

Sucrose*, maize starch, calcium sulfate dihydrate, pregelatinized maize starch, dried maize starch, stearic acid, colloidal anhydrous silicon dioxide, acacia, sodium carboxymethylcellulose, carnauba wax, titanium dioxide, sodium benzoate, povidone, industrial methylated spirit, shellac, acetylated monoglyceride.

*Sucrose: 295.8 mg/tablet.

Nurofen for Children Suspension

Each 5 ml suspension contains:

Active Ingredient

Ibuprofen 100 mg

Other Ingredients

Xanthan gum, sodium citrate, citric acid, orange flavor, sodium saccharin, sodium chloride, maltitol syrup, glycerin, polysorbate 80, domiphen bromide, purified water.

Mechanism of Action

Ibuprofen is a non-steroidal anti-inflammatory agent (NSAIA) that possesses analgesic and antipyretic properties.

The use of ibuprofen is not restricted in patients of advanced age.

Indications**Nurofen Tablets/Liquid Capsules**

Relief of mild to moderate pain such as headache, toothache, menstrual pain, backache, muscular pain, anti-inflammatory for rheumatic diseases, reduction of fever.

Nurofen Forte Tablets

Relief of mild to moderate pain such as headache, toothache, menstrual pain, backache, muscular pain; for the relief of symptoms associated with rheumatic diseases.

Nurofen for Children Suspension

For the reduction of fever and relief of mild to moderate pain. For infants and children aged 3 months to 12 years (i.e. weighing about 40 kg).

Contraindications

Known hypersensitivity to the drug or to any ingredient of the preparation.

Patients with a history of, or existing peptic ulceration.

Patients with severe hepatic failure, severe renal failure, severe heart failure.

Because of potential cross-sensitivity to other NSAIDs, ibuprofen should not be used in patients in whom aspirin or other NSAIDs have induced symptoms of asthma, rhinitis, urticaria, nasal polyps, angioedema, bronchospasm and other symptoms of allergic reactions (anaphylactoid reactions have occurred in such patients).

Warnings

Ibuprofen should be administered under close supervision to patients with a history of upper gastrointestinal tract disease.

If symptoms persist, worsen, or new symptoms develop, the physician should be referred to.

If, following the administration of Nurofen for Children Suspension, symptoms persist for more than 3 days, the physician should be referred to.

Nurofen for Children Suspension is not suitable for children with stomach ulcer or other stomach disorder".

Use in Pregnancy

Administration of ibuprofen is not recommended during pregnancy.

The onset of labor may be delayed and duration of labor increased.

Children under 12 years are unlikely to become pregnant. However, whilst no teratogenic effects have been demonstrated in animal studies, the use of Nurofen for Children should if possible be avoided during pregnancy.

Use in Breastfeeding

Ibuprofen appears in breast milk in very low concentrations and is unlikely to affect the breastfed infant adversely.

Children under 12 years are unlikely to breastfeed.

Use in Pediatrics

Nurofen Tablets/Liquid Capsules and Nurofen Forte Tablets are not to be used in children under 12 years of age.

Nurofen for Children Suspension is not recommended for children under **3 months** of age, unless advised by the physician.

Adverse Reactions

Gastrointestinal

Epigastric pain, heartburn, diarrhea, abdominal distress, nausea and vomiting, indigestion, constipation, abdominal cramps or pain, fullness of gastrointestinal tract, dyspepsia, gastrointestinal bleeding, peptic ulceration,.

Central Nervous System

Dizziness, severe headache, nervousness, convulsions, pain in the spinal column.

Dermatological

Rash (including maculopapular type), pruritus, photosensitivity, skin peeling.

Rarely exfoliative dermatitis and epidermal necrolysis have been reported with ibuprofen.

Special Senses

Hearing disturbance.

Metabolic/Endocrine

Decreased appetite.

Cardiovascular

Edema, fluid retention (generally responds to drug discontinuation, see Precautions).

Hematological

Neutropenia, agranulocytosis, aplastic anemia, hemolytic anemia, thrombocytopenia, decreased hemoglobin and hematocrit.

Allergic

Fever.

Bronchospasm may be precipitated in patients with a history of aspirin-sensitive asthma

Other Hypersensitivity Reactions:

Rarely hypersensitivity reactions with cutaneous eruptions, urticaria and pruritus, as well as attacks of asthma, with or without drop in blood pressure, have been observed. In single cases, severe hypersensitivity reactions, manifesting as facial edema, swelling of the tongue, swelling of the larynx, dyspnea, tachycardia, hypotension or severe shock have been reported. If these symptoms occur, immediate medical attention is necessary.

In single cases, serious forms of skin reactions such as erythema multiforme can occur.

In patients with existing auto-immune disorders (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.

Other

Stiffness, sudden decrease in the amount of urine, black stools.

Renal papillary necrosis which can lead to renal failure.

Precautions

Note

Patients sensitive to one of the non-steroidal anti-inflammatory agents (NSAIDs) may be sensitive to any of the other NSAIDs also.

Blurred and/or diminished vision, scotomata, and changes in color vision have been reported. If a patient develops such complaints while receiving ibuprofen, the drug should be discontinued and the patient should have an ophthalmological examination which includes central visual fields and color vision testing.

As with other NSAIDs, patients should be cautioned about engaging in activities requiring mental alertness and motor coordination, such as driving a car.

Physicians should be consulted if patients taking ibuprofen exhibit signs or symptoms of gastrointestinal ulceration or bleeding, blurred vision or other eye symptoms, skin rash, weight gain, or edema.

Fluid retention and edema have been reported in association with ibuprofen. Therefore, the drug should be used with caution in patients with a history of cardiac decompensation or hypertension.

Since ibuprofen is eliminated primarily by the kidneys, patients with significantly impaired renal function should be closely monitored, and a reduction in dosage should be anticipated to avoid drug accumulation.

Ibuprofen should be used with caution in individuals with intrinsic coagulation defects, and those on anticoagulant therapy.

Caution should be exercised when this product is administered to asthma sufferers since bronchospasm may be precipitated in patients suffering from, or with a previous history of bronchial asthma or allergic disease.

The elderly are at increased risk of the consequence of adverse reactions.

Monitoring of blood urea nitrogen (BUN), serum creatinine concentrations and/or serum potassium concentrations may be required at periodic intervals during therapy, especially in patients with documented hepatic or renal function impairment.

The same monitoring may also be required in patients known or suspected to be at risk for renal function impairment, patients taking diuretics concurrently, and in patients in whom signs of possible renal toxicity occur, such as substantial increases in blood pressure, fluid retention, or rapid weight gain.

In order to avoid exacerbation of disease or adrenal insufficiency, patients who have been on prolonged corticosteroid therapy should have their therapy reduced slowly, rather than discontinued abruptly, when ibuprofen is added to the treatment regimen.

As with other non-steroidal anti-inflammatory agents, borderline elevations of one or more liver tests may occur in up to 15% of patients. These abnormalities may progress, remain essentially unchanged, or be transient with continued therapy.

Because serious gastrointestinal tract ulcerations and bleeding can occur without warning symptoms, physicians should follow chronically treated patients for the signs and symptoms of ulcerations and bleeding and should inform them (in case of children, the child's parent/guardian) of importance of this follow-up.

Patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of more severe hepatic reactions while on therapy with ibuprofen. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with ibuprofen as with other non-steroidal anti-inflammatory agents. Although such reactions are rare, if abnormal liver tests persist or worsen, or clinical signs and symptoms consistent with liver disease develop, or systemic manifestations occur (e.g., eosinophilia, rash, etc.), ibuprofen should be discontinued.

In cross-study comparisons with doses ranging from 1200-3200 mg daily for several weeks, a slight dose-response decrease in hemoglobin/hematocrit was noted.

Aseptic meningitis with fever and coma has been observed on rare occasions in patients on ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases, it has been reported in patients who do not have an underlying chronic disease. If signs or symptoms of meningitis develop in a patient on ibuprofen, the possibility of its being related to ibuprofen should be considered.

Patients Who Require Surgery (Including Dental Surgery)

Caution is recommended in patients who require surgery. Most of the Nonsteroidal anti-inflammatory agents inhibit platelet aggregation and may prolong bleeding time, which may increase intra-and postoperative bleeding. Consideration should therefore be given to discontinuing NSAIDs treatment for an appropriate length of time prior to elective surgery, depending on the potency and duration of effect of the individual agent on platelet aggregability.

In case of patients requiring dental surgery, nonsteroidal anti-inflammatory agents may cause soreness, irritation, or ulceration of the oral mucosa. Most of the nonsteroidal anti-inflammatory agents may rarely cause leukopenia and/or thrombocytopenia, which may result in an increased incidence of microbial infection, delayed healing, and gingival bleeding. If leukopenia or thrombocytopenia occurs, dental work should be deferred until blood counts return to normal, and patients should be instructed in proper oral hygiene.

Each 5 ml of Nurofen For Children Suspension contains 10 mg of sodium saccharin. A quantity of 5 mg/kg body weight/day sodium saccharin should not be exceeded.

Drug Interactions

Ibuprofen/Coumarin-Type Anticoagulants: Because bleeding has been reported when ibuprofen and other non-steroidal anti-inflammatory agents have been administered to patients on coumarin-type anticoagulants, physicians should exercise caution when administering ibuprofen to patients on anticoagulants.

Ibuprofen/Aspirin/Non-Steroidal Anti-Inflammatory Agents (NSAIDs): Animal studies have demonstrated that aspirin administered with NSAIDs causes a decrease in blood levels and activity of non-aspirin drugs. Since concomitant use offers no therapeutic advantage, such combinations should be avoided.

Ibuprofen/Methotrexate: Animal studies indicate that ibuprofen, as well as other NSAIDs, may enhance the toxicity of methotrexate. Caution should be used if ibuprofen is administered concomitantly with methotrexate.

Ibuprofen/Beta-Blockers: As with other nonsteroidal anti-inflammatory agents, the antihypertensive effect of beta-blockers may be reduced.

Ibuprofen/Furosemide/Thiazides: Clinical studies, as well as random observations, have shown that ibuprofen can reduce the natriuretic effect of furosemide and thiazides in some patients. During concomitant therapy with ibuprofen, patients should be observed closely for signs of renal failure, as well as to assure diuretic efficacy.

Ibuprofen/Lithium: Ibuprofen may produce an elevation of plasma lithium levels and a reduction in renal lithium clearance. Therefore, when ibuprofen and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity.

Ibuprofen/Alcohol: Concomitant use of non-steroidal anti-inflammatory agents with alcohol may increase the risk of gastrointestinal side effects, including ulceration or hemorrhage.

Ibuprofen/Probenecid: Probenecid may decrease excretion and increase the serum concentration of NSAIDs, possibly enhancing effectiveness and/or increasing the potential for toxicity of these agents. A decrease in dosage of the NSAIDs may be considered necessary.

Ibuprofen/Zidovudine: There is evidence of prolonged bleeding time in patients receiving concurrent treatment with zidovudine and ibuprofen.

Dosage and Administration

Notes

Nurofen Tablets, Nurofen Forte Tablets, Nurofen Liquid Capsules, and Nurofen for Children Suspension should be taken with or after food.

The tablets/Liquid Capsules should not to be used for more than 10 days for the treatment of pain, or for more than 3 days for the treatment of fever, unless instructed by the physician.

In primary dysmenorrhea, Nurofen Tablets, Nurofen Liquid Capsules, and Nurofen Forte Tablets should be taken immediately following the onset of pain.

Nurofen for Children Suspension

Use the appropriate measuring spoon/dosing syringe provided with the product.

Nurofen For Children Suspension is intended for short-term use only.

Infants and children aged 3 months to 2 years of age: dosage according to physician's prescription only.

Nurofen For Children Suspension is not suitable for children under 3 months of age unless deemed necessary by the physician. (see Warnings).

The recommended dose should not be exceeded.

For pain and fever: the daily dosage is 20-30 mg/kg body weight in divided doses; this can be achieved as follows:

WEIGHT	AGE	DOSAGE	REMARKS
5.6-7.6 kg	Infants 3-6 months	2.5 ml 3 times in 24 hours	According to physician's prescription only
7-9 kg	Infants 6 to 12 months of age	2.5 ml, 3 - 4 times in 24 hours	
10-14 kg	Children 1 to 2 years of age	5 ml, 3 times in 24 hours	
11-15 kg	Children 2 to 3 years of age	5 ml, 3 to 4 times in 24 hours	OTC
16-20 kg	Children 4 to 6 years of age	7.5 ml 3 to 4 times in 24 hours	OTC
21-28 kg	Children 7 to 9 years of age	10 ml, 3 to 4 times in 24 hours	OTC
29-40 kg	Children 10 to 12 years of age	15 ml, 3 to 4 times in 24 hours	OTC

For post immunization pyrexia: 2.5 ml followed by a further 2.5 ml, 6 hours later if necessary. No more than 2x 2.5 ml should be taken in 24 hours. If the fever is not reduced the physician should be referred to.

Nurofen Tablets*Adults and Children 12 Years of Age and Over*

1-2 tablets initially The recommended dose should not be exceeded; then if needed, 1-2 tablets , every 4-6 hours.
Not to exceed 6 tablets in 24 hours.

Nurofen Liquid Capsules

Adults and Children Over 12 Years of Age: 1-2 Liquid Capsules every 4-6 hours as long as symptoms persist.

If the pain and the fever are not relieved, then 2 capsules may be taken. Not to exceed 6 capsules in 24 hours.

Children under 12 Years of Age

Under medical supervision only.

Nurofen Forte Tablets*Adults and Children 12 Years of Age and Over*

1 tablet, 2-4 times daily.

The recommended dose should not be exceeded.

Use in the Elderly

No special dosage modifications are required, unless renal or hepatic function is impaired, in which case dosage should be assessed individually.

Overdosage*Manifestations*

Symptoms include nausea, headache, vomiting, dizziness, drowsiness, nystagmus, blurred vision, tinnitus, and, rarely, hypotension, metabolic acidosis, renal failure, and, loss of consciousness. Large overdoses are generally well tolerated when no other drugs are involved.

Treatment

No special antidote is available.

Patients should be treated symptomatically as required. Use supportive care where appropriate. Within one hour of ingestion, activated charcoal or gastric lavage followed by activated charcoal if the dose is greater than 400 mg/kg, can be used.

Presentation*Nurofen Tablets*

12, 24, 48, and 96 tablets.

Nurofen Liquid Capsules

20 and 40 Liquid Capsules.

Nurofen Forte Tablets

12 and 24 tablets.

Nurofen for Children Suspension

Bottles of 100 ml with a dosing syringe or two-ended measuring spoon of 2.5 ml and 5 ml.

Manufacturer

Boots Healthcare International
Nottingham, England

Importer

Abic Marketing Ltd
P.O.Box 8077, Netanya.