NUFEN SUSPENSION 100mg/5ml

Composition:
Each 5ml suspension contains 100mg Ibuprofen
Preservatives: Sodium benzoate 10.0 mg, Methylparaben 5.0 mg and Propyl paraben 2.5mg.

Description:
An orange colored suspension having fruity flavour.

Pharmacodynamic:
Ibuprofen is a phenylpropionic acid derivative, which has analgesic anti-inflammatory and antipyretic actions. These actions are thought to be from its inhibitory effect on the enzyme cyclo-oxygenase which results in a reduction in prostaglandin synthesis.

Pharmacokinetic:
The peak plasma concentration is about 1 to 2 hours after ingestion. The half-life is about 2 hours.
It is metabolised to 2 inactive metabolites and these are rapidly excreted in urine. About 1% is excreted in urine as unchanged ibuprofen and about 14% as conjugated ibuprofen.
Ibuprofen is extensively bound to plasma proteins.

Indication:
For the relief of fever, e.g. fever associated with cold and flu and pain, e.g. pain from teething and toothache, earache, sore throats, headache and minor aches and sprains. Also for the relief of inflammation of muscles and joints.

Recommended dosage:
Children: The daily dosage of Nufen is 20mg/kg of bodyweight in divided doses. This can be achieved as
follows:
1-2 years: One 2.5 ml spoonful (50mg) three to four times a day
3-7 years: One 5 ml spoonful (100mg) three to four times a day.
8-12 years: Two 5ml spoonful (200mg) three to four times a day.
Not recommended for children weighing less than 7 kg.
Elderly: No special dosage modifications are required unless renal or hepatic function is impaired, in which case dosage should be assessed individually.
After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

Route of administration
Oral administration

Contraindication:
Hypersensitivity to any of the constituents.
Patients with a history of, or existing peptic ulceration.
Patients in whom ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs induce symptoms of asthma, rhinitis or urticaria.

Warning and precaution:
Caution is required if Nufen is administered to patients suffering from, or with previous history of, bronchial asthma since ibuprofen has been reported to cause bronchospasm in such patients. Nufen should only be given with care to patients with history of gastrointestinal disease. Caution is required in patients with renal, hepatic or cardiac impairment since the use of NSAIDs may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored in these patients. Nufen should be given with care to patients with history of heart failure or hypertension since oedema has been reported in association with ibuprofen administration.

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID
Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribes should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Cardiovascular Thrombotic Events
Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events, principally myocardial infarction, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk of an adverse cardiovascular event in patient taking NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration.
There is no consistent evidence that the concurrent use of aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.
Hypertension
NSAIDs may lead to the onset of new hypertension or worsening the pre-existing hypertension and patients taking antihypertensive with NSAIDs may have an impaired anti-hypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.
Heart Failure
Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.
Gastrointestinal Events
All NSAIDs can cause gastrointestinal discomfort and rarely serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation which may increase with dose or duration of use, but can occur at any time without warning. Caution is advised in patients with risk factors for gastrointestinal events e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. When gastrointestinal bleeding or ulcerations occur in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patients about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events.
Severe Skin Reactions
NSAIDs may very rarely cause serious cutaneous adverse events such as exfoliative dermatitis, toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS),

which can be fatal and occur without warning. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients should be advised of the signs and symptoms of serious skin reactions and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.

Drug interaction:
Concurrent aspirin or other NSAIDs may result in an increased incidence of adverse reactions. May enhance the effects of oral anti-coagulants. NSAIDs may diminish the effects of antihypertensives or diuretics, increase plasma lithium levels and reduce clearance of methotrexate.

Pregnancy and lactation:
Children under 12 years are unlikely to become pregnant or breast feed. Nufen Suspension should be avoided during pregnancy although no teratogenic effects have been demonstrated in animal studies. The onset of labour may be delayed and duration of labour increased. Ibuprofen appears in breast milk in very low concentrations and is unlikely to affect the breast fed infant adversely

Side effects:
Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of:

1. non-specific allergic reaction and anaphylaxis.
2. respiratory tract activity comprising of asthma, aggravated asthma, bronchospasm or dyspnea.
3. assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects are rare but may include abdominal pain, nausea, dyspepsia and gastrointestinal bleeding and peptic ulceration. Also very rarely thrombocytopenia has been reported. Bronchospasm may be precipitated in patients with a history of aspirin sensitive asthma.

Overdosage:
Symptoms of overdose include headache, nausea, vomiting, drowsiness, hypotension and loss of consciousness.
Treatment of overdosage should include gastric lavage and if necessary, correction of serum electrolytes and appropriate supportive measures.
There is no specific antidote to ibuprofen.

Effects on ability to drive and use machines
None expected at recommended doses and duration of therapy.

Storage condition:
Store below 30°C.
Shake well before use.
Keep container tightly closed

Presentation:
Amber glass bottles of 60ml, 90ml and 120ml

Manufactured by:
NORIPHARMA SDN BHD 200701034604 (792633-A)
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Date of revision:
March 2021