References

1. Nurofen Cold & Flu Relief 200 mg/30 mg Tablets. Summary of Product Characteristics. November 2021. Accessed September 2022. https://www.medicines.org.uk/emc/product/5626/smpc.

Essential Information:

Nurofen Cold & Flu, Nurofen Sinus Relief. **Active Ingredient (s)**: Each tablet contains 200 mg of ibuprofen and 30mg of Pseudoephedrine Hydrochloride. **Indications**: For the relief of symptoms cold and 'flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses. **Dosage & Administration:** The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. •*Posology:* Adults and children over 12 years: Take 1 or 2 tablets with water, up to three times a day as required. Leave at least 4 hours between doses. Do not take more than 6 tablets in any 24 hour period. Not for use by children under 12 years of age. Do not use for more than 10 days, or if symptoms worsen, without medical advice. •*Method of Administration:* For oral administration with water. **Contraindications**: Hypersensitivity to ibuprofen, pseudoephedrine 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 acetylsalicylic acid (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 coronary heart disease and cardiovascular disorders. Severe hypertension. Severe heart failure, renal failure or hepatic failure (see section 4.4). Last trimester of pregnancy (see section 4.6). Not to be used in children under the age of 12 years. Monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping treatment (see section 4.5). **Special warnings and precautions for use**: Undesirable effects may be minimised by using the lowest effective dose for the shortest possible duration necessary to control symptoms (see GI and cardiovascular risks below). 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 previous history of, bronchial asthma or allergic disease. • Other NSAIDs: The use of Nurofen Cold & Flu with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

• SLE and mixed connective tissue disease: Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis (see section 4.8). • Renal: Moderate to severe renal impairment as renal function may further deteriorate, especially in dehydrated children and adolescents. (see sections 4.3 and 4.8). • Hepatic: Hepatic dysfunction (see sections 4.3 and 4.8). • Cerebrovascular effects: Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of occlusive vascular disease, hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in associated with NSAID therapy. Clinical trial and epidemiological data suggest that the use of ibuprofen, 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). 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, Crohn's disease) as these conditions may be exacerbated (see section 4.8). 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 serious 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 section 4.3), and the elderly. These patients should commence treatment on the lowest dose available. Patients with a history of GI toxicity, particularly when 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 section 4.5). When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn. • Ischaemic colitis: Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other systems or ischaemic colitis develop. •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 for these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases with the first month of treatment. Nurofen Cold & Flu should be discontinued at the first appearance of a skin rash, mucosal lesions, or any other signs of hypersensitivity. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with ibuprofen and pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of Nurofen Cold & Flu should be discontinued and appropriate measures taken if needed. • 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 fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen. To be used with caution in patients with cardiovascular disease, tachycardia, hypertension, angina pectoris, hyperthyroidism, diabetes, phaeochromocytoma, closed angle glaucoma or elevated intraocular pressure, prostatic enlargement, hyperexcitability. To be used with caution in combination with

antihypertensives including adrenergic neurone blockers & Beta blockers (see section 4.5). The effects of a single dose on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment. To be used with caution with other sympathomimetic agents such as decongestants, appetite suppressants and amphetamine-like psycho-stimulants (see section 4.5). If hallucinations, restlessness, or sleep disturbances are experienced whilst taking the product, use of the product should be discontinued. • Ischaemic optic neuropathy: Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. • Excipients: This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. If symptoms persist, consult your doctor. **Fertility, Pregnancy and Lactation:** • *Pregnancy*: Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Nurofen Cold & Flu should, if possible, be avoided during the first 6 months of pregnancy. During the last trimester, ibuprofen is contraindicated 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 the duration increased with an increased bleeding tendency in both mother and child. (see section 4.3). • *Breast feeding:* Although ibuprofen appears in breast milk in very low concentrations, significant amounts of Pseudoephedrine are secreted into breast milk and the use of Nurofen Cold and Flu during lactation should be avoided. **Side effects**:

System Organ Class	Frequency	Adverse Event
Blood and Lymphatic System Disorders	Very rare	Haematopoietic disorders[1]
Immune System Disorders	Uncommon	Hypersensitivity with urticaria and pruritus[2]
	Very rare	Severe hypersensitivity reactions including facial, tongue and throat swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock)[2]
Psychiatric Disorders	Not known	Insomnia, anxiety, restlessness, agitation, hallucination.
Nervous System Disorders	Uncommon	Headache, tremor
	Very rare	Aseptic meningitis[3], Muscular weakness
Cardiac Disorders	Not known	Cardiac failure and oedema[4], tachycardia, arrhythmia, palpitations.
Vascular Disorders	Not known	Hypertension[4]
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory tract reactivity including exacerbation of asthma, bronchospasm or dyspnoea[2].
Gastrointestinal Disorders	Uncommon	Abdominal pain, nausea and dyspepsia[5]
	Rare	Diarrhoea, flatulence, constipation and vomiting

	Very rare	Peptic ulcers, gastrointestinal perforation or gastrointestinal haemorrhage, melaena, haematemesis[6]. Mouth ulceration and gastritis.
	Not known	Dry mouth, exacerbation of colitis and Crohn's disease[7], ischaemic colitis.
Hepatobiliary Disorders	Very rare	Liver disorders
Skin and Subcutaneous Tissue Disorders	Not known	Hyperhidrosis Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Severe skin reactions, including acute generalized exanthematous pustulosis (AGEP) Photosensitivity reactions
	Uncommon	Skin rashes[2]
	Very rare	Bullous reactions, including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis[2]
Musculoskeletal and connective tissue disorders	Not known	Muscular weakness
Renal and Urinary Disorders	Very rare	Acute renal failure[8]
	Not known	Urinary retention
General and Administration Site Conditions	Not known	Chest pain, irritability, thirst,
Metabolism and Nutrition Disorders	Not known	Decreased Appetite
Investigations	Very rare	Haemoglobin decreased
Eye disorders	Not known	Ischaemic optic neuropathy

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