

Essential Information: Nuromol Dual Action Pain Relief 200mg/500mg tablets
PL 00063/0649

Active Ingredient (s): Each tablet contains ibuprofen 200 mg and paracetamol 500 mg.

Indications: For the temporary relief of mild to moderate pain which has not been relieved by ibuprofen or paracetamol individually such as migraine, headache, backache, period pain, dental pain, rheumatic and muscular pain, cold and flu symptoms, sore throat and fever.

Dosage & Administration:

Posology: For short term-use only.

For short term-use only.

Before Nuromol Dual Action is taken, the patient should first try ibuprofen or paracetamol for pain relief in accordance with the product instructions, for the first day of treatment.

If the pain has not been relieved by ibuprofen or paracetamol during the first day of treatment, then the next day Nuromol Dual Action can be taken.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4).

The patient should consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

Adults: One tablet to be taken up to three times per day with water. Leave at least six hours between doses.

If the one tablet dose does not control symptoms, a maximum of two tablets may be taken up to three times a day. Leave at least six hours between doses.

Do not take more than six tablets of Nuromol Dual Action Pain Relief (3000mg Paracetamol, 1200mg Ibuprofen) in any 24 hour period.

To minimise side effects, it is recommended that patients take Nuromol Dual Action Pain Relief with food.

Elderly: No special dosage modifications are required (see section 4.4).

The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used for the shortest possible duration. The patient should be monitored regularly for gastrointestinal bleeding during NSAID therapy.

Not for use by children under 18 years.

Method of Administration: For oral administration

Contraindications:

This product is contraindicated:

- In patients with a known hypersensitivity to ibuprofen, paracetamol or any other excipients in the product.
- In concomitant use with other Paracetamol-containing products – increased risk of serious adverse effects (see Section 4.5).
- In patients with a history of hypersensitivity reactions (e.g. bronchospasm, angioedema, asthma, rhinitis, or urticaria) associated with acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).

- In patients with Active, or a history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- In patients with a history of, or an existing gastrointestinal ulceration/perforation or bleeding, including that associated with NSAIDs (see Section 4.4).
- Patients with defects in coagulation.
- In patients with severe hepatic failure, severe renal failure or severe heart failure (NYHA Class IV) (see Section 4.4).
- In concomitant use with other NSAID containing products, including cyclo-oxygenase-2 (COX-2) specific inhibitors and doses of acetylsalicylic acid above 75 mg daily – increased risk of adverse reactions (see Section 4.5).
- During the last trimester of pregnancy due to risk of premature closure of the foetal ductus arteriosus with possible pulmonary hypertension (see Section 4.6)

Special warnings and precautions for use:

Do not exceed the recommended dose.

Do not use until first trying ibuprofen or paracetamol individually to relieve your pain according to the pack instructions.

Consult a doctor if the symptoms persist or worsen or if the product is required for more than 3 days.

Keep out of the sight and reach of children.

Paracetamol:

The hazards of paracetamol overdose are greater in patients with non-cirrhotic alcoholic liver disease. Immediate medical advice should be sought in the event of an overdose, even if the patient feels well, because of the risk of delayed, serious liver damage.

Do not take with any other paracetamol containing products. Immediate medical advice should be sought if this occurs, even if you feel well as this can result in an overdose (see section 4.9).

Ibuprofen:

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see Section 4.2, and gastrointestinal and cardiovascular risks below) and by patients taking the dose with food (see Section 4.2).

Elderly:

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal (see Section 4.2).

Caution is required in patients with certain conditions:

- Respiratory disorders:

In patients suffering from, or with a history of, bronchial asthma or allergic disease NSAIDs have been reported to precipitate bronchospasm.

- SLE and mixed connective tissue disease:

In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disease disorders there may be an increased risk of aseptic meningitis (see Section 4.8).

- Cardiovascular and cerebrovascular effects

Appropriate monitoring and medical advice are required for patients with a history of hypertension and/or mild to moderate congestive 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 (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (e.g. myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 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 be exercised before initiating long-term treatment for patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) particularly if high doses of ibuprofen (2400 mg/day) are required.

- **Cardiovascular, renal and hepatic impairment:**

The administration of NSAIDs may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients (see Section 4.3).

- **Gastrointestinal effects:**

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).

Gastrointestinal (GI) bleeding, ulceration and 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 in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose acetylsalicylic acid, or other drugs likely to increase gastrointestinal risk (see below and 4.5).

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 acetylsalicylic acid (see Section 4.5).

When GI bleeding or ulceration occurs in patients receiving ibuprofen containing products, the treatment should be withdrawn.

- **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 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. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Use of this product should be discontinued at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.

- **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.

- **Impaired female fertility:**

There is limited evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may impair female fertility by an effect on ovulation and is not recommended in women attempting to conceive. This is reversible on withdrawal of treatment. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of the product should be considered.

- **Excipients**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Fertility, Pregnancy and Lactation:

Pregnancy:

There is no experience of use of this product in humans during pregnancy.

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Congenital abnormalities have been reported in association with NSAID administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of ductus arteriosus), use in the last trimester is contraindicated. The onset of labour may be delayed, and duration increased with an increased bleeding tendency in both mother and child (see Section 4.3). NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.

Therefore if possible, the use of this product should be avoided in the first six months of pregnancy and contraindicated in the last three months of pregnancy (see Section 4.3).

Lactation:

Ibuprofen and its metabolites can pass in very small amounts (0.0008% of the maternal dose) into the breast milk. No harmful effects to infants are known.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breastfeeding.

Therefore it is not necessary to interrupt breastfeeding for short-term treatment with the recommended dose of this product.

See Section 4.4 regarding female fertility.

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. Symptoms can include facial, tongue and throat swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema or severe shock) ²
Psychiatric Disorders	Very rare	Confusion, depression and hallucinations
Nervous System Disorders	Uncommon	Headache and dizziness

	Very rare	Aseptic meningitis ³ , paraesthesia, optic neuritis and somnolence
Eye Disorders	Very rare	Visual disturbance
Ear and Labyrinth Disorders	Very rare	Tinnitus and vertigo
Cardiac Disorders	Very rare	Cardiac failure and oedema ⁴
Vascular Disorders	Very rare	Hypertension ⁴
Respiratory and thoracic and mediastinal disorders	Very rare	Respiratory reactivity including: asthma, exacerbation of asthma, bronchospasm and dyspnoea ²
Gastrointestinal Disorders	Common	Abdominal pain, vomiting, diarrhoea, nausea, dyspepsia and abdominal discomfort ⁵
	Uncommon	peptic ulcer, gastrointestinal perforation or gastrointestinal haemorrhage, melaena, haematemesis ⁶ , mouth ulceration, exacerbation of colitis and Crohn's disease ⁷ gastritis, pancreatitis, flatulence and constipation
Hepatobiliary Disorders	Very rare	1) Abnormal liver function, hepatitis and jaundice ⁸
Skin and Subcutaneous Tissue Disorders	Common	Hyperhidrosis
	Uncommon	Various skin rashes ²
	Very rare	Bullous reactions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis ² .Exfoliative dermatoses, purpura, photosensitivity
	Not known	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP) Photosensitivity reactions
Renal and Urinary Disorders	Very rare	Nephrotoxicity in various forms, including interstitial nephritis, nephrotic syndrome, and acute and chronic renal failure ⁹

General Disorders and Administration Site Conditions	Very rare	Fatigue and malaise
Investigations	Common	Alanine aminotransferase increased, gamma-glutamyltransferase increased and liver function tests abnormal with paracetamol. Blood creatinine increased, blood urea increased.
	Uncommon	Aspartate aminotransferase increased, blood alkaline phosphatase increased, blood creatine phosphokinase increased, haemoglobin decreased and platelet count increased.

Legal Classification: GSL

Licence Holder: Reckitt Benckiser Healthcare (UK) Limited, Slough, SL1 3UH

Licence Number: PL 00063/0649

Price (ex VAT): £3.99 for 12 tablets

Last Revised: 16/08/2021

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. or search for the MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) ltd on: 0333 200 5345