

## **New Zealand Data Sheet**

### **This medicine is not currently marketed in New Zealand**

#### **NUROFEN<sup>®</sup> MIGRAINE 400 DOUBLE STRENGTH** Ibuprofen Lysine 684mg (equiv. ibuprofen 400mg)

#### *PRESENTATION*

White capsule shaped tablet with "N684" printed in black on one face.

#### *USES*

##### **Actions**

Ibuprofen lysine is a non-steroidal anti-inflammatory drug (NSAID).

##### **Pharmacodynamics/Mechanism of action**

Ibuprofen possesses analgesic, antipyretic and anti-inflammatory properties, similar to other non-steroidal anti-inflammatory drugs (NSAIDs). Its mechanism of action is unknown, but is thought to be through peripheral inhibition of cyclooxygenases and subsequent prostaglandin synthetase inhibition.

##### **Pharmacokinetics**

Ibuprofen is well absorbed from the gastrointestinal tract. It is highly bound (90-99%) to plasma proteins and is extensively metabolised to inactive compounds in the liver, mainly by glucuronidation. Both the inactive metabolites and a small amount of unchanged ibuprofen are excreted rapidly and completely by the kidney, with 95% of the administered dose eliminated in the urine within four hours of ingestion. The elimination half-life of ibuprofen is in the range of 1.9 to 2.2 hours.

##### **Indications**

Nurofen Migraine 400 Double Strength is indicated for the temporary relief of pain associated with migraine.

#### *DOSAGE*

Adults and Children 12 years & over: One caplet to be taken with or without food. If necessary, repeat every 4 – 6 hours (maximum 3 caplets in 24 hours). Nurofen Migraine 400 Double Strength should not be used for more than a few days, except on medical advice.

Not recommended for children under 12.

#### *CONTRAINDICATIONS*

Ibuprofen is contraindicated for use in patients with:

- known hypersensitivity or idiosyncratic reaction to ibuprofen (or any of the other ingredients in the product)
- known hypersensitivity to aspirin and other NSAIDs
- asthma that is aspirin or NSAID sensitive
- active gastrointestinal bleeding or peptic ulceration

Use of ibuprofen is contraindicated during the third trimester of pregnancy.

Ibuprofen should not be taken with other products containing ibuprofen or with other anti-inflammatory medicines.

Refer to 'Interactions with other medicines' for additional information

## ***WARNINGS AND PRECAUTIONS***

Ibuprofen should be used with caution in patients with:

- previous history of gastrointestinal haemorrhage or ulcers
- asthma who have not previously taken an NSAID
- hepatic, renal or cardiac impairment.
- pregnancy (see use in pregnancy)

Ibuprofen should be taken with caution with other products containing aspirin and salicylates

Refer to 'Interactions with other medicines' for additional information.

### **Use in pregnancy**

Category C: Ibuprofen inhibits prostaglandin synthesis and, when given during the latter part of pregnancy, may cause closure of the foetal ductus arteriosus, foetal renal impairment, inhibition of platelet aggregation and may delay labour and birth. Use of ibuprofen is thus contraindicated during the third trimester of pregnancy, including the last few days before expected birth.

Further, there is insufficient experience about the safety of use of ibuprofen in humans during pregnancy. Nurofen Migraine 400 Double Strength should therefore not be used during the first 6 months of pregnancy unless the potential benefits to the patient outweigh the possible risk to the foetus.

### **Lactation**

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

Nurofen Migraine 400 Double Strength is unlikely to produce an effect on the ability to drive or use machinery.

### **Use in the elderly**

Ibuprofen should not be taken by adults over the age of 65 without careful consideration of co-morbidities and co-medications because of an increased risk of adverse effects, in particular heart failure, gastro-intestinal ulceration and renal impairment.

## ***ADVERSE EFFECTS***

Adverse effects with non-prescription (OTC) or short-term use ibuprofen are rare and may include:

- gastrointestinal – dyspepsia, heartburn, nausea, loss of appetite, stomach pain, diarrhoea
- central nervous system (CNS) – dizziness, fatigue, headache, nervousness
- hypersensitivity reactions - skin rashes and itching. Rarely exfoliative dermatitis and epidermal necrolysis have been reported with ibuprofen.
- rare cases of photosensitivity
- cardiovascular - fluid retention and in some cases oedema. These effects are rare at non-prescription doses

Allergic reactions such as skin rash, itching, swelling of the face or breathing difficulties may also occur. These are usually transient and reversible on cessation of treatment.

## ***INTERACTION WITH OTHER MEDICINES***

The following interactions with ibuprofen have been noted:

- anticoagulants, including warfarin – ibuprofen interferes with the stability of INR and may increase risk of severe bleeding and sometimes fatal haemorrhage, especially from the gastrointestinal tract. Ibuprofen should only be used in patients taking warfarin if absolutely necessary and they must be closely monitored.
- Ibuprofen may decrease renal clearance and increase plasma concentration of lithium
- Ibuprofen may reduce the anti-hypertensive effect of ACE inhibitors, beta-blockers and diuretics and may cause natriuresis and hyperkalemia in patients under these treatments
- Ibuprofen reduces methotrexate clearance
- Ibuprofen may increase plasma levels of cardiac glycoside
- Ibuprofen may increase the risk of gastrointestinal bleeding especially if taken with corticosteroids
- Ibuprofen may prolong bleeding time in patients treated with zidovudine

Ibuprofen may also interact with probenecid, antidiabetic medicines and phenytoin.

## ***OVERDOSAGE***

In case of overdose, immediately contact the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand call 0800 764 766) for advice.

## ***PHARMACEUTICAL PRECAUTIONS***

Store below 25°C.

## ***MEDICINE CLASSIFICATION***

Pharmacist only medicine

## ***PACKAGE QUANTITIES***

Packs of 8, 10, 12, 20, 24, 30, 36, 40, 48 and 50.

## ***FURTHER INFORMATION***

Inactive ingredients: Povidone, sodium starch glycollate – type A, magnesium stearate, hypromellose, talc, Opaspray white M-1-7111B, Black printing ink.

## ***NAME AND ADDRESS***

Distributed in New Zealand by:  
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## ***DATE OF PREPARATION***

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