

# CORE IBUPROFEN PRODUCT INFORMATION

## Product description

*This section should include:*

- a description of the dosage form;
- a list of the active ingredients expressed quantitatively; and
- a list of the excipients expressed qualitatively

## Pharmacology

### 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.

### 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.

## Indications

*This section must contain the indications of the product as specified in the ARTG. If the indications are not specified in the ARTG (e.g. for a non-validated grandfathered product), the indications must be as specified on the product label.*

## 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

**Comment [MSOffice1]:** This repeats the line below.

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

## 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.

**Comment [MSOffice2]:** We think this is a contraindication.

## 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. [Product name] 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.

## 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.

## 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.

## **Adverse reactions**

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.

## **Dosage**

*This section must contain the current dosage instructions of the registered product, as specified on the product label.*

Ibuprofen should not be used for more than a few days at a time except on medical advice.

## **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.

## **Presentation**

*Information should be included on:*

- *the presentation, including dosage form and pack sizes;*
- *identifying details (eg. colour, shape, identifying markings);*
- *poisons schedule details; and*
- *name and address of the sponsor*

*Include the date of approval as the date on which the notification application is lodged*