

1.3.2 Consumer medicines information

PACKAGE LEAFLET

Package leaflet: Information for the user

Dolomed ® Ibuprofen Liquicaps
Ibuprofen 400 mg

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ibuprofen Capsules is and what it is used for
2. What you need to know before you take Ibuprofen Capsules
3. How to take Ibuprofen Capsules
4. Possible side effects
5. How to store Ibuprofen Capsules
6. Contents of the pack and other information

1. What Ibuprofen capsules is and what it is used for

The active ingredient (which makes the medicine work) is Ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling and high temperature.

Ibuprofen Capsules are used for the relief of:

- Headaches and migraine pain
- Dental pain
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold and flu
- The pain of non-serious arthritis

2. What you need to know before you take Ibuprofen Capsules

Do not take Ibuprofen Capsules if you:

- are allergic to anti-inflammatory medicines
- are allergic to ibuprofen or any of the other ingredients (see section 6), or to aspirin or other painkillers
- have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding
- have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking Ibuprofen, aspirin or similar medicines
- have had gastrointestinal bleeding or perforation when previously taking NSAIDs (non-steroidal antiinflammatory drugs)
- are already taking other NSAID painkillers or more than 75mg of aspirin a day
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are trying to become pregnant except on doctor's advice.
- are in the last 3 months of pregnancy
- are under 12 years old

Please see your doctor or pharmacist before taking this medicine if you:

- have or have had asthma
- have kidney, heart, liver or bowel problems
- have high cholesterol or previously have had a heart attack or stroke
- have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease)
- have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders)
- are a smoker
- are in the first 6 months of pregnancy

Taking other medicines:

To reduce the risk of side effects do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen..)

Some medicines may affect or be affected by treatment with ibuprofen.

Avoid taking this product with corticosteroid tablets, quinolone antibiotics, or drugs that are

prescribed:

- to thin your blood or prevent (e.g. warfarin)
- to stimulate your heart (e.g. glycosides) or treat high blood pressure
- to help you passing water (diuretics)
- for the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, tacrolimus)
- for mania or depression (e.g. Lithium or SSRIs)
- for pregnancy termination (e.g. mifepristone)
- for HIV treatment (e.g. zidovudine)

Speak to your pharmacist or doctor before taking Ibuprofen with other medicines**Other warnings**

- Ibuprofen Capsules belong to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is unlikely that Ibuprofen Capsules, used occasionally, will affect your chances of becoming pregnant. However, tell your doctor before taking this medicine if you have problems becoming pregnant.
- Medicines such as Ibuprofen Capsules may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose.
- If you have heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker), you should discuss your treatment with your doctor or pharmacist.
- There is a risk of renal impairment in dehydrated children and adolescents.

Pregnancy and breast-feeding

Do not use if trying to become pregnant except on doctor's advice.

Do not take in the last 3 months of pregnancy or if you are breastfeeding.

Speak to your doctor if you are in the first 6 months of pregnancy.

3. How to take Ibuprofen Capsules

This product is intended for short term use only. You should only take the lowest dose for the shortest time necessary to relieve your symptoms.

If you are aged between 12 and 18 years and the product is required for more than 3 days or if the symptoms worsen, you should contact your doctor.

The recommended dose for

Adults, older people and children and adolescents between 12-18 years of age: 1 capsule, every 4 to 6 hours as necessary. The recommended interval between doses is approximately 6 to 8 hours, and you must leave at least 4 hours between doses. Do not take more than 3 capsules (1200 mg of ibuprofen) in any 24-hour period. The capsules should be taken with water. Do not chew.

If you take more Ibuprofen Capsules than you should or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken. Bring the remaining capsules with you to show the doctor.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

Do not use for more than a few days at a time except on doctor's advice.

If you forget to take **Ibuprofen Capsules**

Do not take a double dose to make up for a forgotten dose.

If you have questions regarding the use of **Ibuprofen Capsules**, ask your doctor or pharmacist.

4. Possible side effects

STOP taking the medicine and seek immediate medical help if you develop:

- **Signs of intestinal bleeding** such bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds
- **Signs of serious allergic reaction** such as:
 - difficulties in breathing or unexplained wheezing, dizziness or faster heartbeat
 - severe skin reaction (rashes, itchiness, peeling, flaking or blistering), swelling of your face or throat

- Tell your doctor if you experience:
 - Fever, ‘flu-like symptoms, sore throat, mouth ulcers, headache, a stiff neck, vomiting, unexplained bleeding and bruising, severe exhaustion.
 - Indigestion, stomach or abdominal pain, constipation, diarrhoea, flatulence or if you feel sick, chest pain or fast, irregular heartbeat
 - Liver and kidney problems associated with swelling in your arms and legs.

Medicines such as **Ibuprofen Capsules** may be associated with a small increased risk of heart attack (‘myocardial infarction’) or stroke (see section 2, ‘other warnings’).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

5. How to store Ibuprofen Capsules 400mg

Keep all medicines out of sight and reach of children.

Do not use after the expiry date printed on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Protect from light and moisture. Store in the original pack.

Contents of the pack and other information

What Ibuprofen Capsules 400mg contains

The active substance is Ibuprofen. Each soft capsule contains 400 mg Ibuprofen.

The other ingredients are:

Inside the capsule: Potassium Hydroxide, Macrogol 600 and Purified water

Capsule shell: Gelatin, Liquid Sorbitol and Purified water.

What Ibuprofen Capsules 400mg looks like and contents of the pack

Ibuprofen Capsules 400mg are Natural coloured, oval shaped transparent soft gelatin capsules containing clear slightly yellow liquid.

They are available in packs of 10, 20, 24 and 48 capsules.

Sponsor Details

Dolomed® Ibuprofen Liquicaps is Distributed in Australia by:

Distributed in New Zealand by:

Noru Pharma Limited
48B Arundel Street
Mount Roskill
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Date of Preparation

This leaflet was prepared on 6th September 2023