

Ibuprofen 400

Read all of this leaflet carefully before you start taking 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What are Ibuprofen Tablets and what are they used for
2. Before you take Ibuprofen Tablets
3. How to take Ibuprofen Tablets
4. Possible side effects
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1. WHAT ARE IBUPROFEN TABLETS AND WHAT ARE THEY USED FOR

This medicine contains Ibuprofen, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which act to relieve pain, reduce inflammation and lower temperatures when you are feverish. It can be used to relieve headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain, pain of non-serious arthritic conditions, dysmenorrhoea and neuralgia. It can also be used to reduce fever and relieve the symptoms of cold and influenza.

2. BEFORE YOU TAKE IBUPROFEN TABLETS

Medicines such as Ibuprofen Tablets may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (10 days).

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for

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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

Do not take Ibuprofen Tablets

- have an active or a history of recurrent peptic ulcers (more than two).
- have a history of gastrointestinal bleeding or perforation related to the use of NSAIDs.
- have a history of allergy to ibuprofen, aspirin or NSAIDs, which includes attacks of asthma, swelling of the face and throat, skin rashes or a runny nose.
- have a history of allergy to any of the other ingredients in this medicine.
- have severe heart, kidney or liver failure.
- are in your last trimester of pregnancy

See your doctor before you take these tablets

- you suffer from asthma or hives.
- You are pregnant or breast-feeding. Ibuprofen Tablets should be avoided during the first 6 months of pregnancy
- You suffer from Systemic Lupus Erythematosus (SLE) and mixed connective tissue disorders.
- You suffer from ulcerative colitis or Crohns disease as these conditions may be worsened.

Low dose Aspirin

Do not take this medicine if you are taking aspirin at doses of above 75 mg daily. If you are on low-dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take Ibuprofen Tablets.

The Elderly

The elderly have an increased frequency of side effects, especially gastrointestinal bleeding. Consult your doctor before taking this medicine.

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Fertility

Ibuprofen Tablets belong to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen Tablets, used occasionally, will affect your chances of becoming pregnant, however tell your doctor before taking this medicine if you have problems becoming pregnant.

Can you take Ibuprofen Tablets with any other medicines

Before you take these tablets, please tell your doctor or pharmacist about ANY other medicines that you are taking, in particular the following:

- Any other NSAIDs.
- Anti-coagulants (medicines that thin the blood/ prevent clotting i.e. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- Medicines that reduce high blood pressure (ACE Inhibitors i.e. captopril, beta-blockers such as atenolol, or angiotensin-11 receptor antagonists such as losartan).
- Lithium (used in the treatment of mania).
- Diuretics (water tablets).
- Corticosteroids (used to treat hormone problems, inflammation or allergic conditions).
- Ciclosporin (used following organ transplants).
- Mifepristone (used to induce abortion).
- Antibiotics called quinolones (such as Ciprofloxacin).
- Selective serotonin reuptake inhibitor (antidepressants such as Prozac).
- Cardiac Glycoside used in the treatments of congestive heart failure and cardiac arrhythmia.
- Methotrexate, Tacrolimus and Zidovudine

3. HOW TO TAKE IBUPROFEN TABLETS

They are suitable for adults, the elderly and children over 12 years old:

Take one to two tablets with water to start with, preferably with or after food, followed by one to two tablets every four hours if necessary up to three times a day.

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Do not take more than six tablets in any twenty four hour period.

Adults, the elderly and children over 12 years:

This product is intended for short term use only. You should take the lowest dose of the shortest time necessary to relieve your symptoms. You should not take Ibuprofen Tablets for longer than 10 days unless your doctor tells you to. If symptoms persist or worsen consult your doctor.

DO NOT GIVE TO CHILDREN UNDER 12 YEARS OLD

IF YOU HAVE TAKEN TOO MANY TABLETS CONSULT YOUR DOCTOR IMMEDIATELY

4. POSSIBLE SIDE EFFECTS

Most people can take this medicine without any problems but sometimes you may notice some side effects.

If you suffer from any of the following at any time during your treatment STOP TAKING the medicine and seek immediate medical help:

- Pass blood in your faeces (stools/motions).
- Pass black tarry stools.
- Vomit any blood or dark particles that look like coffee grounds.
- Very rarely, severe allergic (hypersensitivity) reactions may occur, such as shock, swelling of the face, tongue and throat, difficulty breathing, faster heart beat and low blood pressure.
- Other allergic reactions such as skin rashes and itching, runny nose, asthma and, very rarely, severe skin reactions such as skin peeling.

STOP TAKING the medicine and tell your doctor if you experience:

- Indigestion or heartburn.
- Abdominal pain (pains in your stomach) or other abnormal stomach symptoms.
- Meningitis (eg stiff neck, fever, disorientation). These other effects are less serious. If you have concerns over these, talk to a pharmacist:
- Sick feeling, nausea and peptic ulcer.
- Rarely changes in the blood which may lead to bruising.

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- Blood disorders where the first signs are fever, sore throat, mouth ulcers, flu-like symptoms, exhaustion.
- Blood in urine, kidney damage or kidney failure has been reported.
- High blood pressure, heart failure.
- Fluid retention which may cause swelling of limbs.
- Rarely liver problems, diarrhoea, wind, constipation and worsening of Crohns or colitis.
- Headache
- A worsening of a previous asthmatic condition.
- Medicines such as ibuprofen may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

If you experience these or any other unusual side effects, stop taking this medicine and tell your doctor or pharmacist at once.

5. HOW TO STORE IBUPROFEN TABLETS

Keep out of the reach and sight of children.

Do not use Ibuprofen Tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use Ibuprofen Tablets if you notice that the pack is damaged or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ibuprofen Tablet contains?

The **Active** substance in your tablet is Ibuprofen. The **Other** ingredients are Microcrystalline cellulose, Maize starch, Gelatin, Methyl Paraben, Propyl Paraben, Purified water, Talcum, Sodium Starch Glycolate, Aerosil, Magnesium Sterate, Ready coat pink, Isopropyl Alcohol,

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Methylene Dichloride.

What Ibuprofen Tablet looks like and contents of the pack?

Ibuprofen Tablets are Pink Coloured round film coated tablet having one side break line and other side plain of each tablet.

A blister of 10 Tablets , such 10 blisters are pack in an carton along with insert.

Patient Information Leaflet

ABOUT THIS MEDICATION

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Merit Organics Ltd

509, 5th Floor, Western Edge I,

Western Express Highway

Borivali East

Mumbai - 400 066

India

Manufacturer

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The leaflet does not contain all the information about your medicine. If you have any questions ask your doctor or pharmacist.