

Advil* 200mg Tablets

Ibuprofen

Please read this leaflet carefully before you start to take your tablets. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

What is this Medicine?

The name of this medicine is Advil 200mg Tablets.

Each coated tablet contains the following active ingredient:
Ibuprofen 200 mg.

In addition to the above active ingredient, Advil Tablets also contain:

Maize Starch, Pregelatinised Starch, Colloidal Anhydrous Silica, Stearic Acid, Corn Starch Grade 826, Croscarmellose Sodium, Sodium Laurilsulfate, Microcrystalline Cellulose, Carnauba wax. Sucrose, Titanium Dioxide (E171), Red Iron Oxide (E172). Povidone, Sodium Benzoate (E211), Methyl Parahydroxybenzoate (E218). Propyl Parahydroxybenzoate (E216), Shellac, Soya Lecithin, Acetylated Monoglyceride, Black Iron Oxide (E172) and Antifoam.

Advil Tablets contain ibuprofen which belongs to a group of medicines which work by changing the body's chemical response to pain, swelling and fever.

Pack Size: 4, 10, 20 tablets.

Product Authorisation Holder
Pfizer Healthcare Ireland,
9 Riverwalk,
National Digital Park,
Citywest Business Campus,
Dublin 24,
Ireland.

Advil Tablets are manufactured for Pfizer Consumer Healthcare Ltd by:
Pfizer Consumer Manufacturing Italy S.r.l.,
Aprilia,
Italy.

Advil Tablets are for the symptomatic treatment of headache, minor aches and pains associated with the common cold and flu, muscular pain, back ache, period pain and dental pain.

BEFORE YOU TAKE THIS MEDICINE YOU MUST INFORM YOUR DOCTOR OR

PHARMACIST IF ANY OF THE FOLLOWING APPLIES TO YOU:

- You are allergic to Ibuprofen, aspirin or similar drugs
- You suffer from asthma
- You are already taking any other medicines from your doctor
- You are taking medicine for the treatment of depression called selective serotonin reuptake inhibitors (SSRIs), water tablets, or corticosteroids
- You are elderly and have had kidney trouble
- You have reacted badly to any of the ingredients in Advil Tablets
- You are pregnant or breast feeding
- You have had or are suffering from inflammatory bowel disease (e.g. ulcerative colitis or Crohn's disease)
- You are 12-18 years old as there is a risk of renal impairment. Therefore ask a doctor before use if a 12-18 year old has not been drinking fluids or has lost fluids due to continuous vomiting or diarrhoea
- You have heart problems including heart failure, angina (chest pain) or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- You have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Take special care with Advil 200 mg Tablets

Skin reactions

Serious skin reactions have been reported in association with Advil 200 mg Tablets treatment. You should stop taking Advil 200 mg Tablets and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.

Medicines such as Advil 200 mg Tablets may be associated with a small increased risk of heart attack or stroke, particularly when used at high dose. Do not exceed the recommended dose or duration of treatment.

Other medicines and Advil 200 mg Tablets:

Advil 200 mg Tablets may affect or be affected by some other medicines.

For example:

Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).

Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan).

Some other medicines may affect or be affected by treatment with Advil 200 mg Tablets . You should therefore always seek the advice of your doctor or pharmacist before you use Advil 200 mg Tablets with other medicines.

Do not take this medicine if:

- You have a stomach ulcer, bleeding from the stomach or other stomach complaint
- You are taking other NSAIDs, aspirin or pain relievers
- You have heart disease or high blood pressure

During chicken pox (varicella) it is advisable to avoid the use of ibuprofen.

This medicine contains Methyl Parahydroxybenzoate (E218) and Propyl Parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicines as it contains sucrose.

Medicines containing ibuprofen may be associated with a small risk of heart attack or stroke. Any risk is likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment as outlined below under 'How to take your medicine.'

Ibuprofen belongs to a group of medicines called NSAIDs. Taking NSAIDs may make it more difficult to become pregnant, but this effect is reversible on stopping the medicine. You should inform your doctor if you are planning to become pregnant or if you have problems in becoming pregnant.

How to take your medicine

Adults, the elderly and young persons over 12 years: Two tablets every 4-6 hours as required to a maximum of six tablets in 24 hours. Tablets should be taken with water.

Children under 12 years: Not recommended.

- If symptoms persist for more than 3 days or become worse, consult your doctor
- Keep out of the reach of children
- Do not exceed the stated dose – an overdose is dangerous

If you take more Advil 200 mg Tablets 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 tablets 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.

Overdose

If you have taken too much of this medicine, you should consult your doctor or hospital immediately.

Possible side effects

As with all medicines, some people may experience undesirable effects. If you experience any of the undesirable effects below, or any other undesirable effects, stop taking this medicine immediately and inform your doctor or pharmacist.

Gastro-intestinal: Nausea, vomiting, diarrhoea, flatulence, constipation, digestive problems, abdominal pain, blackening of stools, vomiting blood, ulceration of mouth and worsening of existing inflammatory bowel disease, peptic ulcers, bleeding or inflammation of the stomach or bowel.

Heart: Small increased risk of heart attack or stroke, raised blood pressure, swollen ankles, chest pain, fast or irregular heart beat. Any risk is more likely with high doses and prolonged treatment.

Skin: Rashes, itching, fluid build up in the tissue below the skin and in mucous membranes which appear as spots or lumps, blood blisters and occasionally flaking of the skin.

Blood: Most frequently the blood does not clot as well, which may result in easy bruising or bleeding, and occasionally anaemia.

Kidney: Blood in the urine, kidney damage and kidney failure have been reported.

Breathing: Wheezing and breathing difficulties may be triggered in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Liver: Abnormal liver function tests, jaundice, inflammation of the liver and occasional liver failure.

Other: Weight gain, headache, ringing in the ear, dizziness and vertigo, visual disturbances, depression, confusion, hallucinations and generalised allergic reactions, including sudden collapse have been reported.

A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Advil 200 mg Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.

IF YOU EXPERIENCE ANY OF THE FOLLOWING, STOP TAKING THE MEDICINE IMMEDIATELY AND TELL YOUR DOCTOR:

Unexplained wheezing, shortness of breath, skin rash, itching, bruising, or facial swelling. These can all be signs that you are allergic to this product.

Unknown frequency:

- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

Storing your medicine

You should not use this medicine after the expiry date shown on the carton / strip of tablets.

Keep this medicine out of the reach and sight of children.

Do not store above 25°C.

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*Trade Mark