



Information for the user

Ibuprofen 200 mg Liquid Capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you
- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice
- 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 must talk to a doctor if you do not feel better or if you feel worse

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1. What this medicine is for

This medicine contains ibuprofen, which belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). They are designed to provide effective relief from rheumatic or muscular pain, backache, neuralgia (sharp pain along nerves), migraine, headache, dental pain, period pain, feverishness, cold and flu symptoms.

2. Before you take this medicine

This medicine can be taken by adults and adolescents (aged 12-18 years old). However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

X Do not take:

- **If you have a stomach ulcer, perforation or bleeding stomach**, or have had one twice or more in the past
- **If you have perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- **If you are allergic** to ibuprofen, peanut, soya or any of the other ingredients of this medicine (listed in section 6), aspirin or other non-steroidal anti-inflammatory medicines (you have ever had asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **If you are taking aspirin with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines
- **If you have severe heart, kidney or liver failure**
- **If you have an intolerance to some sugars**, unless the doctor tells you to (this medicine contains sorbitol)
- If you are in the last 3 months of pregnancy.

Warnings and precautions

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately this medicine and contact immediately your doctor or medical emergencies if you notice any of these signs.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used in high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking this medicine if 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")
- have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- are elderly because you may be at more risk of having serious side effects, particularly stomach problems
- have or have suffered from asthma or have allergies
- have liver or kidney problems
- have stomach or bowel disorders including Crohn's disease or a condition known as ulcerative colitis
- have Systemic Lupus Erythematosus (SLE) – an illness which affects your immune system. It causes joint pains, skin changes and problems with other parts of your body
- are in the first 6 months of pregnancy
- are an adolescent and this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted
- have an infection - please see heading 'Infections' below.

There is a risk of renal impairment in dehydrated adolescents.

If you are taking Ibuprofen 200mg Liquid Capsules for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Infections

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Skin reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reactions with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop using ibuprofen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Tell your doctor if you become pregnant whilst taking this medicine. Do not take this medicine in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not use this medicine in the first 6 months of pregnancy, unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, ibuprofen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if you are breast-feeding.

Fertility

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

Driving and using machines

This medicine is unlikely to cause any effect on your ability to drive or use machines.

This medicine contains sorbitol

This medicine contains 55.63 mg sorbitol in each capsule. If you have an intolerance to some sugars, contact your doctor before taking this product.

This medicine contains soya lecithin

If you are allergic to peanut or soya, do not use this medicinal product.

This medicine contains Ponceau 4R (E124)

It may cause allergic reactions.

Other medicines and this medicine

Before you take these capsules, make sure that you tell your doctor or pharmacist about ANY other medicines you might be using at the same time. Ibuprofen may affect or be affected by some other medicines. For example:

- Other painkillers
- Aspirin 75 mg (to prevent heart attacks and strokes) – the protection may be reduced when you take ibuprofen
- Medicines to thin your blood (e.g. warfarin, ticlopidine)
- Mifepristone (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days
- Water tablets (diuretics)
- Medicines to treat high blood pressure (e.g. ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan), medicines for heart problems
- Corticosteroids (for pain and swelling)
- Lithium (for bipolar disorder)
- Methotrexate (for cancer, psoriasis, or rheumatism)
- Zidovudine (for HIV infection)
- Quinolone antibiotics (for infections)

- Medicines for depression
- Ciclosporin and tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

Some other medicines may also affect or be affected by the treatment of ibuprofen. You should therefore always seek the advice of your doctor or pharmacist before you use ibuprofen with any other medicines, including herbal or homeopathic remedies.

Some medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine), some medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan), and other medicines may affect or be affected by treatment with ibuprofen. You should therefore always seek advice of your doctor or pharmacist before you take ibuprofen with other medicines.

3. How to take this medicine

Check the foil is not broken before first use. If it is, do not take that capsule

Age	How many to take	How often to take them
Adults, the elderly and adolescents	One or two capsules	Every 4 hours, if you need to. Don't take more than 6 capsules in 24 hours.
This medicine is for short-term use only. Take the lowest amount for the shortest possible time to relieve your symptoms.		

Swallow each capsule with water.

Do not chew.

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

If your symptoms worsen at any time, talk to your doctor.

Adults: If your symptoms do not go away within 10 days, talk to your doctor.

Adolescents (aged 12-18 years old): If your symptoms do not go away within 3 days, talk to your doctor.

If you forget to take the capsules: Take them as soon as you remember. Do not make up for the missed capsules by taking more than the amount recommended in the table.

! If you take more capsules than you should: If you have taken more capsules than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

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.

4. Possible side effects

Most people will not have problems, but some may get some .

If you are elderly you may be more likely to have some of these side effects.

! STOP TAKING the medicine and seek immediate medical help if you:

- pass blood in your faeces (stools/motions)
- pass black tarry stools
- vomit any blood or dark particles that look like coffee grounds
- have reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
- have a widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- have a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis)
- experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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
- skin problems
- liver, kidney problems or difficulty urinating.

Medicines such as Ibuprofen 200mg Liquid Capsules may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Ibuprofen 200mg Liquid Capsules, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

STOP TAKING the capsules and contact your doctor immediately if you develop any of the following symptoms at any time while taking your medicine:

Uncommon (may affect up to 1 in 100 people) side effects are:

- itchy skin or rashes, urticaria (hives)
- abdominal pain, nausea (feeling sick), stomach and bowel problems
- headache.

Rare (may affect up to 1 in 1,000 people) side effects are:

- wind (flatulence), diarrhoea, constipation, vomiting.

Very rare (may affect up to 1 in 10,000 people) side effects are:

- kidney failure, problems in the blood cell production: the first signs can be fever, sore throat, mouth ulcers, flu like symptoms, severe exhaustion, unexplained bleeding and bruising
- meningitis (inflammation of the membrane around the brain) symptoms such as fever and chills, severe headache, nausea and vomiting and stiff neck (in patients with inflammatory disease of connective tissue in the skin or joints (systemic lupus erythematosus))
- peptic ulcer, perforation or stomach and intestinal bleeding (gastrointestinal haemorrhage), black tarry stools, vomit of blood or dark particles, inflammation of the mouth (ulcerative stomatitis), inflammation of the stomach (gastritis)
- low blood pressure (hypotension)
- fast heart rate (tachycardia)
- life threatening allergy (anaphylaxis)

- facial or tongue or larynx swelling
- stomach ulcer
- severe forms of skin reactions such as skin rash with redness and blistering (e.g. Stevens-Johnson syndrome), skin peeling (toxic epidermal necrolysis)
- kidney damage (papillary necrosis) resulting in increased urea concentration in the blood and swelling (oedema)
- decreased haemoglobin (a blood protein) levels.

Side effects with frequency not known:

- swelling (oedema), high blood pressure (hypertension) and heart failure
- worsening of colitis or Crohn's disease (inflammation of the bowel)
- worsening of asthma (difficulty in breathing) unexplained wheezing or shortness of breath
- skin becomes sensitive to light
- skin problems:

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). 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 this medicine if you develop these symptoms and seek medical attention immediately. See also section 2.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing the medicine

Do not store above 25°C. Store in the original package.

Keep out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Use by the date on the end flap of the carton.

6. Contents of the pack and other information

Each soft gelatin capsule contains Ibuprofen 200mg, which is the active ingredient.

As well as the active ingredient, the capsules also contain macrogol 600, potassium hydroxide, gelatine, sorbitol, purified water, titanium dioxide, isopropyl alcohol, propylene glycol, hypromellose and ponceau 4R (E124).

The pack contains 16 oval pink capsules with 'I200' printed in white.

Who makes this medicine

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder: Patheon Softgels B.V., De Posthoornstraat 7, 5048 AS Tilburg, The Netherlands.

Manufacturer: Wrafton Laboratories Ltd. Exeter Rd, Wrafton, Braunton, North Devon EX33 2DL United Kingdom.

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If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA

Other formats

To request a copy of this leaflet in Braille, large print or audio please call free of charge:
0800 198 5000 (UK only)

Please be ready to give the following information:

Product Name: Boots Ibuprofen 200 mg Liquid Capsules

Reference Number: 14338/0001

This is a service provided by the Royal National Institute of Blind People.

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