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Ibuprofen 200 mg Coated Tablets

+well Pharmaceuticals

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
This medicine is available without prescription. However, you still need to use Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets carefully to get the best results from them.
Keep this leaflet. You may want to read it again.
If you have any further questions after you have read it, ask your doctor or pharmacist.
You must contact a doctor if your symptoms worsen or do not improve after 3 days for children and adolescents between 12 and 18 years and after 10 days for adults.
If any side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets are and what they are used for
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1. What Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets are and what they are used for

Ibuprofen is one of a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs, which work by changing the body's response to pain, swelling and high temperature. These tablets are used to provide relief of headache, muscular pain, rheumatic pain, pain of non serious arthritic conditions, backache, neuralgia (nerve pain), migraine, period pain, dental pain, feverishness and the symptoms of cold and flu.

2. What you need to know before you take Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets

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. Immediately stop taking this medicine and contact your doctor or medical emergencies if you notice any of these signs.

Do not take Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets if you:
- have had an allergic reaction to aspirin, Ibuprofen, any other NSAIDs or any of the ingredients (see section 6 for further information)
- have ever had 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 Anti-inflammatory Drugs)
- are taking other NSAIDs (Non-steroidal Anti-inflammatory Drugs)
- are taking more than 75 mg Aspirin a day. If you are on low dose aspirin (up to 75 mg daily) speak to your doctor or pharmacist before you take this medicine
- have severe liver or kidney problems
- have heart problems, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are in the last 3 months of pregnancy
- are under 12 years of age.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets if you:
- have or 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
- have an infection - please see heading “Infections” below.

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

Infections
Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets may hide signs of infections such as fever and pain. It is therefore possible that Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets 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.

Other medicines and Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. To reduce the risk of side effects, do not take this product with other NSAID containing products (e.g. aspirin, ibuprofen), if you are on low-dose aspirin (up to 75 mg daily), speak to your doctor or pharmacist before you take this medicine.

Ibuprofen may affect or be affected by some other medicines
For example:
Avoid taking this product with corticosteroid tablets, quinolone antibiotics or drugs that are prescribed:
- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- To stimulate your heart (e.g. glycosides)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- To help you passing water (diuretics)
- For temporary suppression of your immune system (e.g. methotrexate, ciclosporine, tacrolimus)
- For mania or depression (e.g. lithium or SSRIs)
- For pregnancy termination (e.g. mifepristone)
- For HIV treatment (e.g. zidovudine).

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 other medicines.

Other warnings
- Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets belong to a group of medicines which may **impair fertility in women.** This is reversible on stopping the medicine. It is unlikely that Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets used occasionally will affect your chance of becoming pregnant. However tell your doctor before taking this medicine if you have problems becoming pregnant.
- Anti-inflammatory/pain-killer medicines such as Ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of the treatment.
- You should discuss your treatment with your doctor or pharmacist before you take Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets if you:
  - have heart problems including heart failure, angina (chest pain) or if you have had 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 ischemic attack "TIA").
  - have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke or if you are a smoker.
- There is a risk of kidney problems in dehydrated children and adolescents.

Pregnancy and breast-feeding
Tell your doctor if you become pregnant whilst taking this medicine. Do not take this medicine if you are 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 take this medicine during 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, this medicine 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. Avoid the use of this medicine in the first 6 months of pregnancy, unless the doctor advises otherwise.

Speak to your doctor or pharmacist before taking this medicine if you are breast-feeding.

If you are taking Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets 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 kidney, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

Driving and using machinery
Taking Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets will not affect your ability to drive or use machines.

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Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets contain lactose and sucrose
If you have been told by your doctor that you have an intolerance to some sugars you should not take this medicine.

Advice for patients on a controlled sodium diet
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

Taking with food and drink
Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets should be taken with water, preferably with or after food.

3. How to take Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
This product is intended for short term use only.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.
If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Adults, the elderly and children & adolescents between 12 and 18 years
Dose for Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets:
- 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
- Do not take more than six tablets in any twenty four hour period.
- You should not take Ibuprofen for longer than 10 days unless your doctor tells you to.
  If symptoms persist or the pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.
- If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

Children under 12 years
Do not give Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets to children under 12 years old.

If you take more Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets than you should
If you have taken more Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets than you should, or if children have taken 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 the urine, cold body feeling and breathing problems have been reported.

If you forget to take Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets
Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop using Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets
Please speak to your doctor or pharmacist before stopping this or any medicine.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may be minimised by taking the lowest dose for the shortest time necessary to relieve the symptoms. You may suffer one of the known side effects of NSAIDs (see below), if any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

STOP TAKING the medicine and seek immediate medical help if you develop:
- Signs of intestinal bleeding such as: 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
  - 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).
  - Swelling of your face, tongue or throat.
- Signs of kidney problems such as:
  - Passing less or more urine
  - Cloudy urine or blood in the urine
  - Pain in the back and/or swelling (particularly in the legs).
- Signs of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or consciousness, patients with auto immune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.
- 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 cell).
- Liver, kidney problems or difficulty urinating.

Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets, 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 medicine and tell your doctor if you experience the following uncommon side effects which affect 1 in 100 users:
- Indigestion, heartburn or feeling sick
- Pains in your stomach (abdomen) or other abnormal stomach problems.

TELL YOUR DOCTOR if you have any of the following side effects, they become worse or you notice any effects not listed:
Uncommon: may affect up to 1 in 100 people
- Allergic reactions, such as skin rashes (urticaria), itching, peeling
- Headache.

Rare: may affect up to 1 in 1,000 people
- Flatulence (wind), diarrhoea, constipation and vomiting.

Very rare: may affect up to 1 in 10,000 people
- Blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers, flu-like symptoms and severe exhaustion
- Drop in blood pressure or irregular heartbeat
- Stomach or intestinal ulcers, sometimes with bleeding and perforation, inflammation of the lining of the mouth with ulceration (ulcerative stomatitis), inflammation of the stomach (gastritis)
- Liver problems.

Not known: frequency cannot be estimated from the available data
- Worsening of asthma or bronchospasm
- Swelling (oedema), high blood pressure, heart failure or attack
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Worsening of colitis and Crohn's disease
- 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 Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets if you develop these symptoms and seek medical attention immediately. See also section 2.
- Skin becomes sensitive to light.

Medicines such as Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke, see section 2 "other warnings".

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 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. How to store Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets

Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.
- Do not store above 25ºC
- Store in the original package to protect from moisture.
- 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.

6. Contents of the pack and other information

What does each Well Pharmaceuticals Ibuprofen 200 mg Coated Tablet contain
Each tablet contains the active ingredient Ibuprofen BP 200 mg. Other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, sucrose, talc, hypromellose (HPMC 2910), titanium dioxide (E171), calcium carbonate and carnauba wax.

What Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets look like and contents of the pack
This product contains white round shaped sugar coated tablets. Well Pharmaceuticals Ibuprofen 200 mg Coated Tablets are available in blister packs of 6, 12,16, 24, 48, 84 and 96 tablets.
Not all pack sizes may be marketed.

Produced for:
Well Pharmaceuticals,
Merchants Warehouse, Castle Street,
Manchester, M3 4LZ, UK.

Marketing Authorisation Holder and Manufacturer:
Relonchem Limited,
Cheshire House, Gorsey Lane, Widnes, Cheshire, WA8 0RP, UK.

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