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Ibuprofen 200 mg Soft Capsules
(Ibuprofen)

+well Pharmaceuticals

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules carefully to get the best results from it.

Keep this leaflet. You may need to read it again.
Ask your pharmacist if you need more information or advice.

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 of the side effects gets 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 Soft Capsules are and what they are used for
2. What you need to know before you take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules
3. How to take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules
4. Possible side effects
5. How to store Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules
6. Contents of the pack and other information

1. What Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules are and they are used for

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

Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules is used for the relief of:
- Headache and migraine pain
- Dental pain and neuralgia
- Period pain
- Rheumatic, muscular and back pain
- Feverishness and symptoms of cold & flu.

2. What you need to know before you take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules

This medicine can be taken by adults and children aged 12 years and over. However, some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

Do not take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules if you:
- 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
- are taking other NSAIDs painkillers or more than 75 mg aspirin per day. If you are on low-dose aspirin (up to 75mg daily) speak to your doctor or pharmacist before taking this medicine.
- have severe heart, kidney or liver failure, high blood pressure or blood coagulation disorder
- have breathing difficulties
- are pregnant and in the last **3 months of pregnancy**
- are **under 12 years old.**

Other important information
If you are taking Well Pharmaceuticals Ibuprofen 200 mg Soft 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 'Possible side effects'). 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 taking this medicine immediately and immediately contact your doctor or medical emergency department if you notice any of these signs.

Risk of heart attack or stroke
Anti-inflammatory/painkiller medicines like 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 treatment.

Take special care with Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules
Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and 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.

Talk to your pharmacist or doctor if:
- you have asthma, a history of asthma or other allergic disease, bowel problems, ulcerative colitis, Crohn's disease
- you are between 12 and 18 years old and you are dehydrated, you may get kidney problems
- you have kidney problems (these can be made worse if you are dehydrated, especially if you are elderly, or between 12 and 18 years old)
- you have other heart or liver problems (see "Do not take")
- you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
- you have chickenpox
- 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") - see "**Risk of heart attack or stroke**" under "Other important information"
- you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- you are in the first 6 months of pregnancy
- you have an infection - please see heading "**Infections**".

Infections
Ibuprofen may hide signs of infections such as fever and pain. It is therefore possible that Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules 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 Soft Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal and homeopathic remedies.

- other painkillers (including NSAIDs)
- aspirin up to 75 mg (to prevent heart attacks or 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 e.g. cardiac glycoside
- corticosteroids, lithium, methotrexate, zidovudine
- quinolone antibiotics (for infections)
- medicines for depression (including SSRIs)
- ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism).

Pregnancy
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.

Breast-feeding
Do not take if you are breast-feeding.

Women of childbearing age
This medicine belongs to a group of medicines which may **impair fertility in women**. This 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 machinery
Taking Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules will not affect your ability to drive or use machines.

Important information about some of the ingredients of this medicine
This medicine contains:
- Ponceau 4R red (E124). May cause allergic reactions.
- 58.6 mg of **sorbitol**, a source of 14.7 mg of **fructose** per capsule. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
- 17.4 mg of **potassium** per capsule; to be taken into consideration by patients on a controlled **potassium** diet.

3. How to take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules

This medicine is 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).

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Adults, the elderly and adolescents of 12 to 18 years
Take 1 or 2 capsules with water, up to three times a day as required.
Leave at least four hours between doses.

Adults and the elderly
If this medicinal product is required for more than 10 days, or if symptoms persist or worsen, contact your doctor.

Adolescents
If this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.
Do not take more than 6 capsules in 24 hours.
Do not give to children under 12 years.
Do not take for longer than 10 days unless your doctor tells you to. If symptoms persist or pain or fever worsen, or if any new symptoms occur, consult your doctor or pharmacist.

If you have taken more Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules 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.

Take your medicine and this leaflet with you.
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.

If you forget to take Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules
Refer to the directions above on how to take this medicine and do not take more than advised.

4. Possible side effects

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

STOP TAKING the medicine and seek immediate medical help if you develop:
- **signs of intestinal bleeding** such as: bright red faeces (stools), black tarry stools, vomiting blood or dark particles that look like coffee grounds.
- **signs of serious allergic reaction** such as:
  - breathing difficulties or unexplained wheezing
  - dizziness or faster heartbeat
  - severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering (e.g. Stevens-Johnson syndrome)
  - swelling of your face or throat.
- **signs of kidney problems** such as:
  - passing less or more urine
  - cloudy urine or blood in 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 autoimmune disorders (lupus, mixed connective-tissue disease) may be more likely to be affected.
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- 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].
- **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).

STOP TAKING the medicine and tell your doctor if you experience the following uncommon side effects which may affect up to 1 in 100 people:
- 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
- headaches.

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, headache, stiff neck, vomiting, 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
- worsening of colitis and Crohn's disease
- skin becomes sensitive to light.

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 Soft Capsules if you develop these symptoms and seek medical attention immediately. See also section 2.

Well Pharmaceuticals Ibuprofen 200 mg Soft 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.

Medicines such as Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules may be associated with a small increased risk of heart attack or stroke. (see section 2 'Other important information').

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. Tell your doctor or pharmacist if you notice any of the following:
- Liver, kidney problems or difficulty urinating

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 Website 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 Soft Capsules

Keep this medicine out of the sight and reach of children.
Do not use 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.
Store in the original pack.
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 Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules contain
Each capsule contains 200 mg of the active ingredient Ibuprofen. The other ingredients are macrogol 400, sorbitan mono oleate, sorbitol (E420), potassium hydroxide (E525), gelatin (E441), ponceau 4R red (E124), triglycerides, shellac, titanium dioxide (E171), propylene glycol and water.

What Well Pharmaceuticals Ibuprofen 200 mg Soft Capsules look like and contents of the pack
Wine red colour oval shaped soft gelatin capsules containing pink to dark pink viscous liquid, printed '142' in white colour on capsule shell. Available in blister packs of 10 or 16 capsules.
Not all pack sizes may be marketed.

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

Marketing Authorisation Holder:
Bell, Sons & Co. (Druggists) Ltd., Southport, PR9 9AL, UK.

Manufacturer:
Relonchem Limited,
Cheshire House, Gorsey Lane, Widnes, Cheshire, WA8 0RP, UK.

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