Pharmacode

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Package leaflet: Information for the user

Ibuprofen 600 mg coated tablets

(Ibuprofen)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

1. **What Ibuprofen 600 mg coated tablets are and what they are used for**
2. **What you need to know before you take Ibuprofen 600 mg coated tablets**
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1. WHAT IBUPROFEN 600 MG COATED TABLETS ARE AND WHAT THEY ARE USED FOR

Ibuprofen belongs to a group of medicines called anti-inflammatory painkillers. Ibuprofen is used in the treatment of painful and inflammatory conditions, such as mild to moderate pain, osteoarthritis, rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), arthritis of the spine, inflammation of the spine (ankylosing spondylitis), swollen joints, frozen shoulder, bursitis, tendinitis, tenosynovitis, lower back pain, sprains and strains.

Ibuprofen 600 mg coated tablets can also be used to treat other painful conditions such as toothache, pain after operations, period pain and headache, including migraine.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IBUPROFEN 600 MG COATED TABLETS

Do not take Ibuprofen 600 mg coated tablets if you:
- are allergic to ibuprofen or any of the other ingredients of this medicine (listed in the section 6)
- currently have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation in the past
- have had bleeding in your stomach when previously taking NSAIDs (non-steroidal anti-inflammatory drugs)
- have a condition which increases your tendency to bleeding
- suffer from severe liver, kidney or heart failure
- have ever had an allergic reaction (such as a runny nose, swelling or hives) or suffered wheezing on taking ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs
- have asthma
- are pregnant or planning to become pregnant or you are breast-feeding Ibuprofen 600 mg coated tablets may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Warning and precautions
Talk to your doctor or pharmacist before taking Ibuprofen 600 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. Stop immediately Ibuprofen 600 mg coated tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

Medicines like Ibuprofen 600 mg coated tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

If you are taking Ibuprofen 600 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 kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4). Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen 600 mg coated tablets if you:
- have heart problems including heart failure, angina (chest pain) or you have had a heart attack, bypass surgery or peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries)
- have any kind of stroke or think that you might be at risk of these conditions (for example if you have a family history of heart disease or stroke, high blood pressure, diabetes or high cholesterol or are a smoker)

Talk to your doctor or pharmacist before taking Ibuprofen 600 mg coated tablets if you:
- have systemic lupus erythematosus (SLE, sometimes known as lupus) or a connective tissue disease (autoimmune diseases affecting connective tissue)
- have chicken pox or shingles.
- or your child is dehydrated. There is a risk of kidney damage in dehydrated children adolescents and the elderly.
- have an infection - please see heading "Infections" below.

Infections
Ibuprofen 600 mg coated tablets may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen 600 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.

Skin reaction
Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with Ibuprofen 600 mg coated tablets treatment. You should stop using Ibuprofen 600 mg coated tablets and seek medical attention immediately, if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Ibuprofen 600 mg coated Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Ibuprofen 600 mg coated Tablets may affect or be affected by other medicines. For example:
- medicines that are anticoagulants (used to thin the blood or prevent clotting, such as aspirin/acetylsalicylic acid, warfarin and ticlopidine)
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, or angiotensin-II receptor antagonists such as losartan)
- diuretics (water tablets)
- cardiac glycosides (used to treat heart conditions, such as digoxin)
- any other anti-inflammatory pain killer (including aspirin)
- lithium (used to treat depression)
- methotrexate (used to treat certain cancers and rheumatoid arthritis)
- zidovudine (an anti-viral drug)
- steroids (used in the treatment of inflammatory conditions)
- medicines known as immunosuppressants (such as ciclosporin and tacrolimus) used to dampen down your immune response
- medicines known as selective serotonin reuptake inhibitors (SSRIs) (used for the treatment of depression)
- antibiotics called quinolones (such as ciprofloxacin)
- aminoglycosides (a type of antibiotic)
- mifepristone (used to induce abortion)
- any other ibuprofen preparations, such as those you can buy without a prescription
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas (used to treat diabetes, such as glibenclamide)
- voriconazole or fluconazole (types of anti-fungal drugs)
- gingko biloba, a herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

Ibuprofen 600 mg coated tablets with alcohol:
Ibuprofen 600 mg coated tablets may cause some side effects including dizziness, drowsiness and stomach problems such as bleeding in the stomach. Drinking excessive alcohol with Ibuprofen 600 mg coated tablets might make these side effects worse.

Pregnancy and breast-feeding
Do not take Ibuprofen 600 mg coated tablets 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 Ibuprofen 600 mg coated tablets 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, Ibuprofen 600 mg coated tablets 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.

Driving and using machines
Ibuprofen tablets may make you feel dizzy or drowsy. If the tablets affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

Ibuprofen 600 mg coated tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

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3. HOW TO TAKE IBUPROFEN 600 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.

Take your Ibuprofen 600 mg coated tablets with or after food, with a glass of water. Ibuprofen 600 mg coated tablets should be swallowed whole and not chewed, broken, crushed or sucked to help prevent discomfort in the mouth or irritation in the throat. 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).

The recommended dose is:
Adults:
The usual dosage is 600 to 1800 mg spread throughout the day. Your doctor may choose to increase this depending on what you are being treated for; but no more than 2400 mg should be taken in one day.

Children over 12 years:
The usual dosage is 20 mg/kg bodyweight daily, given in divided doses.
In case of severe juvenile rheumatoid arthritis your doctor may increase the dosage up to 40 mg/kg in divided doses.
Ibuprofen tablets should not be taken by children weighing less than 7 kg.
Ibuprofen 600 mg tablets should not be given to children under the age of 12 years.

You should avoid excessive use of painkillers. If you usually take painkillers, especially combinations of different painkillers, you may damage your kidneys, **tell your doctor if you are already taking another painkiller before taking this medicine and your doctor will decide whether you should take this medicine**. This risk may be increased if you are dehydrated.

The use of painkillers for a long period of time has in some patients been linked to headaches, a condition called medication overuse headache (MOH). Patients who have frequent or daily headaches despite (or because of) the regular use of pain killers should not be treated with increased doses of Ibuprofen Tablets. Tell your doctor if you have been having headaches while taking this medicine.

If you take more Ibuprofen 600 mg coated tablets than you should
If you have taken more Ibuprofen 600 mg coated tablets 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 of overdose can include nausea, stomach pain, vomiting (may be blood streaked), gastrointestinal bleeding (see also part 4 below), diarrhoea, headache, ringing in the ears, confusion and shaky eye movement. Also, agitation, somnolence, disorientation or coma may occur. Occasionally patients develop convulsions. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, low levels of potassium in your blood, cold body feeling, and breathing problems have been reported. Further, the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics. Furthermore, there may be low blood pressure and reduced breathing.

If you forget to take Ibuprofen 600 mg coated tablets
Take them as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them. If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

You can minimise the risk of side effects by taking the least amount of tablets for the shortest amount of time necessary to control your symptoms.

STOP TAKING Ibuprofen 600 mg coated tablets and seek immediate medical help if you develop any of the following:
- 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].
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
- 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 generalised exanthematous pustulosis).
- signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light
- passing blood in your faeces (stools/motions)
- passing black tarry stools
- vomiting any blood or dark particles that look like coffee grounds

Tell your doctor and stop taking the Ibuprofen 600 mg coated tablets if you experience:
- chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.
- unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting
- unexplained wheezing, shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction)
- loss of vision, blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations)
- liver, kidney problems or difficulty urinating.

Ibuprofen 600 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.
Medicines such as Ibuprofen 600 mg coated tablets have been associated with a small increased risk of high blood pressure, heart attack (myocardial infarction) or stroke or heart failure.
Medicines such as Ibuprofen 600 mg coated tablets have in exceptional cases been associated with severe skin problems for patients with chicken pox or shingles.

Blood disorders such as reduction in blood cells and platelet counts
- the first signs are: high temperature, sore throat, mouth ulcers, flu-like symptoms, bleeding from the mouth, nose, ear and the skin.

Ibuprofen has also been shown to sometimes worsen the symptoms of Crohn's disease or colitis.

Other side effects
Common (may affect up to 1 in 10 people):
- feeling dizzy or tired
- diarrhoea, wind, constipation
- headache - if this happens while you are taking this medicine it is important not to take any other medicines for pain to help with this.

Uncommon (may affect up to 1 in 100 people):
- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives
- skin becomes sensitive to light
- hearing problems
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- ringing in ears (tinnitus)
- sensation of spinning (vertigo)
- mouth ulcers

Rare (may affect up to 1 in 1,000 people)
- feeling depressed or confused

Very rare (may affect up to 1 in 10,000 people)
- inflammation of the pancreas

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 App or Apple App Store. By reporting side affects you can help provide more information on the safety of this medicine.

5. HOW TO STORE IBUPROFEN 600 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 carton. The expiry date refers to the last day of that month.

Do not store your medicine above 25°C. Store in the original package. Keep the container tightly closed.

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 Ibuprofen 600 mg coated tablets contain:
The active substance is ibuprofen. Each tablet contains 600 mg of ibuprofen.
The other ingredients are povidone, lactose, maize starch, microcrystalline cellulose, sodium starch glycollate, colloidal anhydrous silica, Opalux Pink AS-1537 (sucrose, erythrosine (E127), titanium dioxide (E171), talc, sodium benzoate (E211)), triethyl citrate, macrogol 4000 and ammonio methacrylate copolymer type A.

What Ibuprofen 600 mg coated tablets looks like and contents of the pack:
Ibuprofen 600 mg coated tablets are pink capsule shaped, film-coated tablets with a Chatfield logo imprinted on one side and IBUPR 600 on the other side.
They are available in containers of 14, 15, 21, 28, 42, 50, 56, 70, 84, 100, 250 and 500 tablets and blister packs of 14, 15, 21, 28, 42, 50, 56, 70 and 84 tablets.

Not all pack sizes may be marketed.

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