

## Package leaflet: Information for the user

### Ibuprofen 200mg Coated Tablets ibuprofen

(Referred to as Ibuprofen tablets in the remainder of the leaflet)

#### 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, pharmacist or nurse 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. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days (for children 12 years and over) or 10 days (for adults).

#### What is in this leaflet

1. What Ibuprofen tablets are and what they are used for
2. What you need to know before you take Ibuprofen tablets
3. How to take Ibuprofen tablets
4. Possible side effects
5. How to store Ibuprofen tablets
6. Contents of the pack and other information

#### 1. What Ibuprofen tablets are and what they are used for

The name of your medicine is Ibuprofen tablets. The active ingredient in your medicine is ibuprofen. Ibuprofen belongs to a group of medicines called Non-

Steroidal Anti-inflammatory Drugs (NSAIDs). Ibuprofen works by reducing inflammation and relieving pain



including period pain, nerve related pain (neuralgia), dental pain, headaches and migraine, backache, swelling and stiffness in the joints and muscles (rheumatic and muscular pain), fever and cold and flu symptoms.

#### 2. What you need to know before you take Ibuprofen tablets

##### Do not take Ibuprofen tablets if you:

- are allergic (hypersensitive), or have had an allergic reaction to, ibuprofen, any other NSAID, aspirin, or to any of the other ingredients in this medicine (listed in section 6). Symptoms of an allergic reaction may include swollen eyelids, lips, tongue, or throat
- have ever had a worsening of symptoms of asthma (breathing difficulty), hayfever (runny, itchy and inflamed nose with sneezing), urticaria (an itchy rash), or angioedema (swelling under the skin) when taking ibuprofen, aspirin or similar painkillers
- currently have or have had a stomach ulcer or bleeding in the stomach on two previous occasions
- have ever had perforation or bleeding of the gut when taking any NSAID
- suffer from severe liver, kidney or heart problems
- are in the last 3 months of pregnancy
- 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.

Do not use Ibuprofen tablets if you are in the last 3 months of pregnancy. You should not use Ibuprofen tablets during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of Ibuprofen tablets can cause adverse effects in your unborn baby. It is not known if the same risk applies to Ibuprofen tablets when it is used on the skin.

- have abnormal bleeding or problems with abnormal bruising
- are currently taking mifamurtide (a medicine used to treat bone cancer).

#### Warnings and precautions

##### Take special care with Ibuprofen tablets if you:

- are taking Ibuprofen tablets for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4)
- are elderly, as you may be more prone to side effects (see section 4. Possible Side Effects) which in some cases may be extremely serious or even life threatening
- have a history of asthma or other allergy disorders
- have liver, kidney, or bowel problems
- have Systemic Lupus Erythematosus (SLE), a condition of the immune system resulting in joint pains, skin rashes, kidney or liver problems
- have or have had high blood pressure or heart problems. Speak to your doctor who will advise you on your treatment and may wish to monitor you
- have a history of bleeding in the stomach or gut. Speak to your doctor immediately if you notice any problems with your stomach, especially at the start of your treatment
- smoke
- have an infection, as symptoms such as fever, pain and swelling may be masked
- are a child with chickenpox
- are in the first 6 months of your pregnancy
- are taking other NSAID painkillers including a specific type called COX-2 inhibitors, or aspirin, with a daily dose above 75mg
- if you are on low-dose aspirin (up to 75mg).

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 tablets and contact immediately your doctor or medical emergencies if you notice any of these signs

#### Skin reactions

Serious skin reactions have been reported including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) in association with ibuprofen tablets treatment. You should stop taking Ibuprofen 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.

There is a risk of renal impairment in dehydrated adolescents.

Speak to your doctor or pharmacist before you take this medicine.

Anti-inflammatory/pain-killer 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.

You should discuss your treatment with your doctor or pharmacist before taking Ibuprofen 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
- have an infection – please see heading "Infections" below.

#### Infections

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Ibuprofen may affect or be affected by some other medicines. For example:

- other pain killers including aspirin or other NSAIDs
- medicines used to treat bacterial infections
- medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- medicines used to treat depression, such as selective serotonin re-uptake inhibitors (SSRIs) and lithium
- medicines used to treat diabetes
- medicines used to treat epilepsy
- medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)
- medicines used to treat viral infections, such as zidovudine and ritonavir
- medicines used to treat heart failure
- medicines used to treat various illnesses that involve inflammation in the body (corticosteroids)
- medicines used to treat cancer, such as methotrexate and mifamurtide
- medicines used during abortion, such as mifepristone
- medicines used to relax muscles
- pentoxifylline, used to treat blood circulation problems
- diuretics, medicines used to help you pass water (urine)
- medicines used to suppress the immune system in patients who have had a transplant, such as ciclosporin and tacrolimus
- penicillamine, used to treat a number of conditions such as rheumatoid arthritis, Wilson's disease
- cardiac glycosides, such as digoxin, used to treat heart conditions
- lithium
- antibiotics called quinolones such as ciprofloxacin
- aminoglycosides (a type of antibiotic)
- cholestyramine (a drug used to lower cholesterol)
- medicines known as sulphonylureas such as glibenclamide (used to treat diabetes)
- voriconazole or fluconazole (type of anti-fungal drugs)
- ginkgo biloba herbal medicine (there is a chance you may bleed more easily if you are taking this with ibuprofen).

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.

#### Ibuprofen tablets with alcohol

Do not drink alcohol whilst taking this medicine.

#### Pregnancy, breast-feeding and fertility

Do not take Ibuprofen 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 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 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.

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

Ask your doctor or pharmacist for advice before taking any medicine.

It is possible that this medicine can pass into breast milk. If you are breast-feeding, speak to your doctor or pharmacist for advice before taking this, or any medicine.

#### Driving and using machines

This medicine may make you feel dizzy, drowsy or tired. You may also experience blurry vision. Do not drive or use tools or machines if you are affected in any way after taking this medicine.

#### Ibuprofen tablets contain sucrose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

#### 3. How to take Ibuprofen tablets

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

## Adults, Elderly and Children over 12 years

This product is intended for short term use only. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. You should not take Ibuprofen tablets for longer than 10 days unless your doctor tells you to. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

The usual dose is 200 or 400mg (1 or 2 tablets) to be taken with a drink of water, preferably with or after food, up to three times a day as required. The dose should not be repeated more frequently than every 4 hours. Do not take more than 1200mg (6 tablets) in 24 hours.

Taking this medicine with or after food or milk may only partially reduce stomach side effects such as indigestion (see section 4).

If in adolescents, this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

### If you take more Ibuprofen tablets than you should

If you accidentally take too many Ibuprofen tablets than you should, or if children have taken this medicine by accident, you should contact your doctor or go to your nearest hospital casualty department immediately to get an opinion of the risk and advice on action to be taken. Take this leaflet and any unused tablets with you to show the doctor.

The symptoms of an overdose include vomiting (being sick – may be blood streaked), headache, confusion, shaky eye movement, nausea (feeling sick), stomach pain and possibly diarrhoea. Dizziness, ringing in the ears (tinnitus) and fainting can also be signs of an overdose. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and blood in urine, cold body feeling, and breathing problems have been reported.

The doctor will assess your condition and decide how to treat your overdose.

### If you forget to take Ibuprofen tablets

If you forget to take your medicine take it as soon as you remember. If it is almost time for your next dose do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose.

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.

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. (Drug reaction with eosinophilia and systemic symptoms):

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.)

Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome

Systemic and topical formulations

Severe cutaneous adverse reactions (SCARs)

### STOP TAKING Ibuprofen tablets and seek immediate medical help if you experience:

- Signs of aseptic meningitis such as severe headache, high temperature, stiffness of the neck or intolerance to bright light
- Signs of intestinal bleeding such as
- Passing blood in your faeces (stools/motions)
- Passing black tarry stools
- Vomiting any blood or dark particles that look like coffee grounds
- 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).

### TALK YOUR DOCTOR AND STOP TAKING IBUPROFEN TABLETS IF YOU EXPERIENCE:

- Unexplained stomach pain (abdominal pain) or other abnormal stomach symptoms, indigestion, heartburn, feeling sick and/or vomiting
- Unexplained wheezing or shortness of breath, skin rash, itching or bruising (these may be symptoms of an allergic reaction)
- Yellowing of the eyes and/or skin (jaundice)
- Severe sore throat with high fever (these may be symptoms of a condition known as agranulocytosis)
- Blurred or disturbed vision (visual impairment) or seeing/hearing strange things (hallucinations)
- Fluid retention e.g. swollen ankles (this may be a sign of kidney problems)
- Severe spreading skin rash (Stevens – Johnson Syndrome and erythema multiforme, symptoms include severe skin rash, blistering of skin, including inside mouth, nose, and genitals, as well as skin peeling which may be accompanied with symptoms such as aching, headaches, and feverishness).
- Liver, kidney problems or difficulty urinating

Medicines such as Ibuprofen tablets have been associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Medicines such as Ibuprofen tablets have in exceptional cases been associated with severe skin problems for patients with chikén pox or shingles.

Blood disorders, kidney problems, liver problems or severe skin reactions may occur rarely with ibuprofen.

Very rarely Ibuprofen tablets may cause aseptic meningitis (inflammation of the protective membrane surrounding the brain).

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

Ibuprofen 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 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.

## Other side effects

### Common (affects up to 1 in 10 people):

- rash
- feeling dizzy or tired
- stomach pain, or indigestion, diarrhoea, feeling sick, being sick, 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
- passing black tarry stools
- passing blood in your faeces (stools/motions)
- vomiting any blood.

### Uncommon (affects up to 1 in 100 people):

- feeling drowsy
- feeling anxious
- feeling a tingling sensation or 'pins and needles'
- difficulty sleeping
- hives, itching
- skin becomes sensitive to light
- visual disturbances, hearing problems
- hepatitis, yellowing of your skin or eyes, reduced liver function
- reduced kidney function, inflammation of the kidneys, kidney failure
- sneezing, blocked, itchy or runny nose (rhinitis)
- stomach or gut ulcer, hole in the wall of the digestive tract
- inflammation of your stomach lining
- small bruises on your skin or inside your mouth, nose or ears
- difficulty breathing, wheezing or coughing, asthma or worsening of asthma
- ringing in ears (tinnitus)
- sensation of feeling dizzy or spinning (vertigo)
- mouth ulcers
- serious allergic reaction which causes swelling of the face or throat.

### Rare (affects up to 1 in a 1000 people):

- feeling depressed or confused
- fluid retention (oedema)
- a brain infection called 'non-bacterial meningitis'
- loss of vision
- changes in blood count – the first signs are: high temperature, sore throat, mouth ulcers, flu – like symptoms, feeling very tired, bleeding from the nose and the skin
- reduction in blood cells (anaemia)
- serious allergic reaction which causes difficulty in breathing or dizziness
- severe sore throat with high fever (agranulocytosis).

### Very rare (affects up to 1 in 10,000 people):

- liver failure
- heart failure
- heart attack
- inflammation of the pancreas
- skin problems (which can also affect inside your mouth, nose or ears) such as 'Stevens – Johnson syndrome', 'toxic epidermal necrolysis' or 'erythema multiforme'
- high blood pressure.

### Not known (frequency cannot be estimated from available data):

- worsening of ulcerative colitis or Crohn's Disease (inflammation of the colon)
- 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 Ibuprofen tablets if you develop these symptoms and seek medical attention immediately. See also section 2
- skin becomes sensitive to light
- Fixed drug rash, which may progress to generalised blistering lesions.

### 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](http://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 Ibuprofen 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 blister or carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light and 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 Ibuprofen tablets contain

The active substance is ibuprofen. Each Ibuprofen 200mg Coated Tablet contains 200mg ibuprofen.

The other ingredients are colloidal anhydrous silica, starch, povidone, microcrystalline cellulose, alginate acid, magnesium stearate, sodium lauryl sulfate, sodium starch glycolate and croscarmellose sodium.

The coating contains PVAP sealcote, purified talc, sucrose, calcium carbonate, acacia, titanium dioxide (E171) and carnauba wax.

### What Ibuprofen tablets look like and contents of the pack

Ibuprofen tablets are round, white, sugar coated tablets.

Ibuprofen tablets are available in the following packs:

- blister packs of 8, 12 or 16 tablets
- plastic bottles, in pack sizes of 25, 50, 100, 250, 500, 560 and 1000 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Wrexhardt UK Ltd, Ash Road North, Wrexham LL13 9UF, UK

### Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

### Other formats:

To listen to or 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                   | Reference number |
|--------------------------------|------------------|
| Ibuprofen 200mg Coated Tablets | 29831/0116       |

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

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