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PHARMA CODE XXXX

Pharmacode Reading Direction

Package leaflet: Information for the user

IBUPROFEN 200mg TABLETS
ibuprofen

Please 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.
- 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 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.

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 active ingredient (which makes the medicine work) is Ibuprofen. It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs provide relief by changing the body's response to pain, swelling, and high temperature.
Ibuprofen Tablets are used for the relief of:
- **Headaches and migraine pain**
- **Dental pain and neuralgia**
- **Period pain**
- **Rheumatic, muscular and back pain**
- **Feverishness and symptoms of cold and flu**
- **The pain of non-serious arthritis [for Pharmacy (P) only]**

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE IBUPROFEN TABLETS

Do not take these tablets if you:
- are allergic to ibuprofen or any of the other ingredients (see section 6) or to aspirin or other painkillers
- 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 75mg of aspirin a day. If you are on low-dose aspirin (up to 75mg 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 old

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this product if you:
- have or have 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 rousing 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.
- are taking ibuprofen 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).

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 200 mg Tablets and contact immediately your doctor or medical emergencies if you notice any of these signs.

Take special care with Ibuprofen 200 mg Tablets:
Skin reactions:
Serious skin reactions have been reported in association with Ibuprofen treatment. You should stop taking Ibuprofen 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.
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 treatment. Stop using Ibuprofen 200 mg Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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
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 75mg 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 the temporary suppression of your immune system (e.g. methotrexate, ciclosporin, 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
- Ibuprofen Tablets belongs to a group of medicines which may **Impair fertility in women**. This 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 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 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.
- There is a risk of renal impairment in dehydrated children and adolescents.

Pregnancy and breast feeding
Tell your doctor if you become pregnant whilst taking ibuprofen. 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. Avoid the use of 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. Speak to your doctor or pharmacist before taking this medicine if you are breastfeeding.

Ibuprofen 200mg tablets contain lactose and sucrose
This medicine contains less than 1 mmol sodium (23mg) per two tablets, that is to say essentially 'sodium-free'.
If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking these tablets.

3. HOW TO TAKE IBUPROFEN TABLETS

This product 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).

Adults, the elderly and children & adolescents between 12 and 18 years:
Take 1 or 2 tablets with water, up to three times a day as required.
Leave at least four hours between doses.
Do not take more than 6 tablets in 24 hours.

Do not give to children under 12 years.
In children and adolescents between 12 and 18 years:
If in children and adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

In adults:
Do not take 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 you take more Ibuprofen 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 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 Ibuprofen Tablets
Simply refer to the directions above on how to take the medicine and do not take more than is advised.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ibuprofen 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 gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

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

STOP TAKING the medicine and Seek immediate medical help if you develop:

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 intestinal bleeding such as: bright red faeces (stools/motions), black tarry stools, vomiting blood or dark particles that look like coffee grounds.

Signs or serious allergic reaction such as:
- difficulties in breathing 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.: Steven-Johnson syndrome)
- swelling of your face, tongue 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).

Ibuprofen, 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.

Signs of aseptic meningitis with neck stiffness, headache, feeling sick, being sick, fever or loss of consciousness. Patients with autoimmune 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 cells).

STOP TAKING the medicine and tell your doctor If you experience 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, mouth ulcers, flu-like symptoms and severe exhaustion
- drop in blood pressure or irregular heart beat
- 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 available data:
- worsening of asthma or bronchospasm
- swelling (oedema), high blood pressure, heart failure or attack
- 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 Ibuprofen if you develop these symptoms and seek medical attention immediately. See also section 2.
- skin becomes sensitive to light

Medicines such as Ibuprofen 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 by searching 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

- Blister packaging: This medicinal product does not require any special storage conditions.
- Securitainer/Pharmapac bottles: Store below 25°C, Keep the bottle tightly closed.
- Do not use after the expiry date shown on the package.
- **Keep out of the sight and reach of children**

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Each tablet contains the active ingredient Ibuprofen 200mg. The tablets also contain: lactose monohydrate, maize starch, hypromellose, sodium starch glycollate, colloidal anhydrous silica, magnesium stearate, sucrose, purified talc, titanium dioxide (E171), carnauba wax, coloring agent (sucrose, titanium dioxide (E171), sodium benzoate (E211).

This product contains white, shiny, biconvex, caplet shaped, sugar coated tablets.
Ibuprofen 200 mg Tablets (PL 43461/0122) are available in blister packs of 4, 12 and 16 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, UK

Manufacturer:
Flamingo Pharma (UK) Limited,
The Bloc,
38 Springfield Way,
Anlaby, Hull,
HU10 6RJ, United Kingdom.

If you would like this leaflet in different format information or want to report any side effects please contact marketing authorization holder listed above.

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