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Information for the user**Boots Ibuprofen and Codeine 200 mg/12.8 mg Tablets**
Ibuprofen, Codeine Phosphate Hemihydrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Ibuprofen and Codeine 200 mg/12.8 mg Tablets may be referred to as this medicine throughout this leaflet.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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 within 3 days.

• This medicine can only be used for the short-term treatment of acute moderate pain such as headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia that is not relieved by aspirin, ibuprofen or paracetamol alone.

• This medicine should only be taken when necessary.

• You should only take this medicine for a maximum of 3 days at a time. If you need to take it for longer than 3 days you should see your doctor or pharmacist for advice.

• This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.

• If you take this medicine for headaches for more than 3 days it can make them worse.

1. What Ibuprofen and Codeine 200 mg/12.8 mg Tablets are and what they are used for

The active ingredients (which make this medicine work) are Ibuprofen and Codeine phosphate.

This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

This medicine also contains ibuprofen. Ibuprofen, a non-steroidal anti-inflammatory medicine (NSAID) which also acts to reduce swelling (inflammation).

This medicine can be used in adults and children over 12 years of age, for the short-term treatment of acute moderate pain such as headaches, rheumatic and muscular pain, backache, migraine, period pain, dental pain and neuralgia that is not relieved by aspirin, ibuprofen or paracetamol alone.

2. What you need to know before you take Ibuprofen and Codeine 200 mg/12.8 mg Tablets

This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.

If you take a painkiller for headaches for more than 3 days it can make them worse.

X Do not take Ibuprofen and Codeine Tablets:

• If you have (or have had two or more episodes of) a stomach ulcer, perforation, or bleeding.

• If you have breathing difficulties.

• If you are allergic to ibuprofen, codeine, or any other ingredient of this medicine (listed in section 6), or to aspirin or other painkillers.

• If you suffer from severe liver, kidney or heart problems.

• If you suffer from chronic constipation.

• If you have had gastrointestinal bleeding or perforation when previously taking NSAIDs.

• If you have had a worsening of asthma, skin rash, itchy runny nose or facial swelling when previously taking ibuprofen, aspirin or similar medicines.

• If you are taking other NSAID painkillers or aspirin with a daily dose above 75mg.

• If you are pregnant, and in the last 3 months of pregnancy.

• If you are breastfeeding (see "Other important information")

• If you are under 12 years old.

• If you are taking monoamine oxidase inhibitors or if you have taken them in the last 14 days.

• For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

• If you know that you metabolise very rapidly codeine into morphine.

3. Warnings and precautions

Tolerance, dependence, and addiction

This medicine contains codeine, which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Ibuprofen and Codeine Tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. If you are taking Ibuprofen and Codeine Tablets for longer than the recommended time or at higher than recommended doses the risk of these side effects can increase and you are also at risk of 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).

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Ibuprofen and Codeine Tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").

- You are a smoker.

- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Ibuprofen and Codeine Tablets it could be a sign that you have become dependent or addicted:

- You need to take this medicine for longer than advised by your doctor.

- You need to take more than the recommended dose.

- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

- You are using the medicine for reasons other than prescribed, for instance, "to stay calm" or "help you sleep".

- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.

- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ("withdrawal effects").

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3. When you stop taking Ibuprofen and Codeine Tablets).

! Talk to your doctor or pharmacist before taking Ibuprofen and Codeine Tablets:

- If you have or have had asthma.

- If you are between 12 and 18 years old and you are dehydrated, you may get kidney problems.

- If 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).

- If you have heart, liver or bowel problems or are dehydrated.

- If you have low or high blood pressure.

- If you have a head injury or raised intracranial pressure.

- If you suffer from a thyroid disorder.

- If you have Systemic Lupus Erythematosus (a condition of the immune system causing joint pain, skin changes and other organ disorders).

- If you have a history of gastrointestinal disease (such as ulcerative colitis, Crohn's disease).

- 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").

- If you are pregnant, and in the first 6 months of pregnancy.

- During chicken pox (varicella) as it is advisable to avoid the use of ibuprofen.

- If you have an infection - please see heading "Infections" below.

- If you have gallstones.

- If you suffer from myasthenia gravis (a condition that causes muscle weakness).

- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Infections:

This medicine may hide signs of infections such as fever and pain. It is therefore possible that this medicine 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 reactions:

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.

Sleep-related breathing disorders:

This medicine can cause sleep-related breathing disorders, such as sleep apnoea (breathing pauses during sleep) and sleep related hypopnoea (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Can you take this medicine with other medicines?

You should always seek the advice of your doctor or pharmacist before you take this medicine with any other medicines, including herbal and homeopathic remedies.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This medicine may affect or be affected by some other medicines, for example:

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).

- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol, medicines, angiotensin-II receptor antagonists such as losartan).

- Water tablets (diuretics)

- Medicines for depression or anxiety, including moclobemide, selective serotonin-reuptake inhibitors (SSRIs), selective serotonin- and norepinephrine-reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs) and hydroxyzine.

- Depressants of the central nervous system such as alcohol, anaesthetics, hypnotics, sedatives, tricyclic antidepressants or antipsychotics and phenothiazines.

- Lithium (for bipolar disorder)

- Gabapentin or pregabalin to treat epilepsy or pain due to nerve pain (neuropathic pain)

- Loperamide and kaolin (for diarrhoea)

- Metoclopramide or domperidone (for sickness)

- Cimetidine (for stomach ulcers)

- Quinolone antibiotics (for infections)

- Medicines for heart problems such as quinidine or mexiletine (to treat abnormal heart rhythms)

- Corticosteroids (used for many conditions such as pain, allergy, asthma, rhinitis, skin and eye problems)

- Methotrexate (for cancer, psoriasis, rheumatism, Crohn's disease)

- Zidovudine (for HIV infection)

- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

- Mifepristone (for termination of pregnancy) – do not take ibuprofen if you have taken mifepristone in the last 12 days

Other important information:

Care should be taken in elderly patients due to increased risk of breathing problems.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

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.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, hiccups, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

This medicine belongs to a group of medicines which may impair fertility in women. This is reversible on stopping the medicine. It is not known if 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.

Anti-inflammatory/painkiller medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke. Any risk is more likely with high doses or prolonged treatment. Do not exceed the recommended dose or take for longer than necessary to control your

symptoms (3 days):

If you have heart problems, have had a stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, high cholesterol, or are a smoker), you should discuss this treatment with your doctor or pharmacist.

Do not drink alcohol (wine, beer, spirits): whilst taking this medicine. Alcohol may make you feel more drowsy.

Children and adolescents:

Use in children and adolescents after surgery: Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Use in children with breathing problems: Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Pregnancy and breast-feeding:

Pregnancy: 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 are pregnant for longer than expected.

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: 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.

Very rare: may affect up to 1 in 10,000 people

Uncommon: frequency cannot be estimated from the available data

worsening of asthma

sweating, thirst, muscle weakness or tremors, sleeplessness

fast, irregular