

Information for the user

[BOOTS LOGO] Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets

Ibuprofen, Codeine Phosphate Hemihydrate

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 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 product 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 film-coated tablets are and what they are used for
 2. What you need to know before you take Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets
 3. How to take Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets
 4. Possible side effects
 5. How to store Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets
 6. Contents of the pack and other information

1. What Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets are and what they are used for

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), also acts to reduce swelling (inflammation).

This medicine can 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 codeine-containing medicine can be used in adults and children aged 12 years and over.

2. What you need to know before you take Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets

This medicine contains codeine which can cause addiction (physiological and psychological dependence) if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine (such as restlessness and irritability) when you stop taking it. If you find you need to take this medicine all of the time, it is important to talk to your doctor.

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

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

X Do not take Ibuprofen and Codeine tablets:

- **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
- **If you have a stomach ulcer, perforation or bleeding**, or have had one twice or more in the past
- **If you have had perforation or a bleeding stomach** after taking a non-steroidal anti-inflammatory medicine (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools)
- **If you are allergic** to ibuprofen, codeine, or any other ingredient of this medicine (listed in section 6), aspirin or other non-steroidal anti-inflammatory medicines (you have ever had chest pain, asthma, runny nose, itchy skin or swelling of the lips, face or throat after taking these medicines)
- **If you are taking aspirin with a daily dose above 75 mg**, or other non-steroidal anti-inflammatory medicines
- **If you have severe heart, kidney or liver failure**
- **If you have difficulty breathing** or breathing problems
- **If you have constipation** on a regular basis or are continually constipated
- **If you are pregnant**, and in the last 3 months of pregnancy
- **If you are breastfeeding** (see “Other important information”)

Warnings and precautions

Ibuprofen and Codeine tablets contains codeine, which is an opioid medicine.

Repeated use of Ibuprofen and Codeine tablets may result in you becoming accustomed to it (needing to take higher doses). Repeated use of Ibuprofen and Codeine tablets may 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 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).

If you experience any of the following signs whilst taking Ibuprofen and Codeine tablets, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted:

- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')

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

- If you have asthma, a history of asthma or other allergic disease, bowel problems or Crohn's disease
- If you have other kidney, heart or liver problems (see "Do not take")
- If you have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus)
- If you have low blood pressure or an underactive thyroid
- If you have a head injury or a condition where there is raised pressure in the head
- If you are taking monoamine oxidase inhibitors (MAOIs for depression), or have taken them in the last 14 days
- If you are elderly – you may get more side effects (see back of leaflet)
- If you are taking any other painkillers or receiving regular treatment from your doctor
- 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") – see '**Risk of heart attack or stroke**' below
- If you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker
- 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."

Other important information

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.

Risk of heart attack or stroke: 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.

Take special care with Ibuprofen and Codeine Tablets.

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.

Children and adolescents

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.

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

Infections

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

Other medicines and Ibuprofen and Codeine tablets

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

- Other painkillers (including NSAIDs)
- Aspirin 75 mg (to prevent heart attacks or strokes) – the protection may be reduced when you take ibuprofen
- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)
- Water tablets (diuretics)
- 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 for heart problems

- Corticosteroids (used for many conditions such as pain, swelling, allergy, asthma, rheumatism and skin problems)
- Lithium (for bipolar disorder)
- Methotrexate (for cancer, psoriasis, rheumatism, Crohn's disease)
- Zidovudine (for HIV infection)
- Quinolone antibiotics (for infections)
- Medicines for depression (including SSRIs and MAOIs)
- Ciclosporin or tacrolimus (given after transplant surgery, or for psoriasis or rheumatism)

Some other medicines may also affect or be affected by the treatment of Ibuprofen and Codeine tablets. You should therefore always seek the advice of your doctor or pharmacist before you use this medicine with any other medicines, including herbal and homeopathic remedies.

Ibuprofen and Codeine tablets with alcohol

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

Pregnancy, breast-feeding and fertility

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 need treatment for longer than a few days, your doctor may recommend additional monitoring.

Breast-feeding: Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk.

Fertility: If you take this medicine, it may reduce your ability to become pregnant. This effect will be reversed when you stop taking the medicine.

Driving and using machines

This medicine may cause drowsiness, dizziness or blurred vision. You should not drive or use machines until you are sure you are not affected.

Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets contain sodium

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

3. How to take Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets

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

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).

Check the foil is not broken before use. If it is, do not take that tablet.

Age	How many to take	How often to take them
Children aged 12 years to 18 years	One or two	Every 6 hours, if you need to. Don't take more than 6 tablets in 24 hours.
Adults over 18 years	One or two	Every 4 to 6 hours. Don't take more than 6 tablets in 24 hours. Do not take more often than every 4 hours.

Take the lowest amount for the shortest possible time to relieve your symptoms

Swallow each tablet with water.

Do not take for more than 3 days. If you need to use this medicine for more than 3 days you must speak to your doctor or pharmacist for advice.

Do not take more than the amount recommended above.

If your symptoms worsen at any time, or do not go away within 3 days, you must speak to your doctor or pharmacist.

Use in children

Do not give to children under 12 years, due to the risk of severe breathing problems.

! If you take more Ibuprofen and Codeine tablets than you should

If you have taken more tablets than you should, or if children have taken the medicine by accident always contact a doctor or nearest hospital to get an opinion on 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 and Codeine tablets

If you forget to take the tablets, take them as soon as you remember. Do not make up for the missed tablets by taking more than 2 tablets at a time.

Possible withdrawal effects when stopping treatment

This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. When you stop taking it you may get withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you are elderly you may be more likely to have some of these side effects (especially stomach bleeding which can be fatal in the elderly).

If you have any unwanted side effects you should seek advice from your doctor, pharmacist or healthcare professional.

Stop using this medicine and seek medical attention immediately if you notice any of the following symptoms:

- You are sick and it contains blood or dark particles that look like coffee grounds
- Pass blood in your stools or pass black tarry stools
- Stomach problems including pain, indigestion or heartburn
- Unexplained wheezing (asthma), worsening of existing asthma, difficulty in breathing, swelling of the face, tongue, neck or throat, fast heart rate, feeling faint or dizzy or collapse (severe allergic reaction)
- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
- 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). See also section 2
- Meningitis (e.g. stiff neck, fever, disorientation)
- Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, or feel breathless, very tired or weak, have no appetite, or have swollen ankles)

If you get any of the following side effects see your pharmacist or doctor:

- Feeling sick or being sick
- Headache, blurred vision, drowsiness – do not drive or use machines if you feel drowsy or have blurred vision
- High blood pressure, heart failure (you may be tired, have difficulty breathing or swollen legs)
- Fluid retention, which may cause swelling of the limbs
- Slow or shallow breathing, problems clearing catarrh or phlegm from the chest
- Vary rarely, yellowing of the skin or eyes, pale stools or upper abdominal pain (these may be signs of liver problems)
- Swelling or ulcers of the stomach or mouth lining, constipation
- Rarely, diarrhoea, wind, worsening of colitis or Crohn's disease

- Very rarely, tiredness or severe exhaustion, changes in the blood which may cause unusual bruising or unexplained bleeding and an increase in the number of infections that you get (e.g. sore throats, mouth ulcers, flu-like symptoms including fever)
- A small increased risk of heart attack or stroke if you take large amounts for a long time
- Skin becomes sensitive to light - frequency unknown

Ibuprofen and Codeine 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.

If any side effect becomes severe, or you notice any side effects not listed here, please tell your pharmacist or doctor.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

! How do I know if I am addicted?

If you take the medicine according to the instructions on the pack it is unlikely that you will become addicted to the medicine. **However, if the following apply to you** it is important that you talk to your doctor:

- You need to take the medicine for longer periods of time
- You need to take more than the recommended amount
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again

5. How to store Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets

These film-coated tablets do not require any special storage conditions.

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 foil or flap of the carton.

Do not throw away any medicines via wastewater. 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 and Codeine tablets contain

Each film-coated tablet contains Codeine Phosphate Hemihydrate 12.8 mg and Ibuprofen 200 mg which are the active ingredients.

As well as the active ingredients, the film-coated tablets also contain microcrystalline cellulose, sodium starch glycolate, pregelatinised maize starch, hypromellose. The tablet coating contains hypromellose, titanium dioxide (E171), talc.

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

The pack contains 16 or 24 white capsule-shaped tablets embossed with I+.

Marketing Authorisation Holder

Taw Pharma (Ireland) Limited, 104 Lower Baggot Street, Dublin 2, D02Y940, Ireland

Manufacturer

Custom Pharmaceuticals Ltd Conway Street Hove East Sussex BN3 3LW, UK

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Other sources of information

To request a copy of this leaflet in Braille, large print or audio please call free of charge:

1890 708091 (ROI only)

And ask for Boots Medical Information.

Please be ready to give the following information:

Product Name: Boots Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets

Reference Number: PA23081/004/001