



Information for the user

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

Ibuprofen, Codeine Phosphate Hemihydrate

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription to treat minor conditions. However, you still need to take it carefully to get the best results from it.

- 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
- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

What this medicine is for

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

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

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

Before you take this medicine

- **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 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.

✗ Do not take:

- **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 ingredients of the product, aspirin or other non-steroidal anti-inflammatory medicines (you have ever had 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")

! Talk to your pharmacist or doctor:

- 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

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. **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.

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.

**Pregnancy:** During the last 3 months of pregnancy do not take this medicine. During the first 6 months of pregnancy talk to your pharmacist or doctor.

**Breastfeeding:** Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk.

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

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

**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.

If you take other medicines

Before you take these tablets, make sure that you tell your doctor or pharmacist about ANY other medicines you might be using at the same time. 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.

✓ How to take this medicine

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. <b>Don't take more than 6 tablets in 24 hours.</b>
Adults over 18 years	One or two	Every 4 to 6 hours. <b>Don't take more than 6 tablets in 24 hours.</b> 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 give to children under 12 years, due to the risk of severe breathing problems.

Do not take more than the amount recommended above.

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

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

**! If you take too many tablets:** Talk to a doctor straight away. Take your medicine and this leaflet with you.

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.

Possible side effects

Most people will not have problems, but some people may have side effects when taking this medicine. 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 other healthcare professional.

**! If you get any of these serious side effects, stop taking the tablets. See a doctor at once:**

- 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 reactions)
- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, blistering and lesions of the skin)
- 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
- Very 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

**If any side effect becomes severe, or you notice any side effect 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@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

How to store this medicine

These film-coated tablets do not require any special storage conditions. Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the foil or end flap of the carton. After this date return any unused product to your nearest pharmacy for safe disposal.

What is in this medicine

Each film-coated tablet contains Codeine Phosphate Hemihydrate 12.8 mg, 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.

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

Who makes this medicine

Manufactured for the Marketing Authorisation holder The Boots Company PLC Nottingham NG2 3AA, UK by Custom Pharmaceuticals Ltd Conway Street Hove East Sussex BN3 3LW, UK

Leaflet prepared April 2016

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA, UK

Other formats

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 Pharmaceuticals Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets

Reference Number: PA 4/66/1

PACK MOCK UP		
Product Name:	Ibuprofen and Codeine 200 mg/12.8 mg film-coated tablets	
Product Licence No.:	PA 4/66/1	
Wording Ref:	Internally approved v3 dated 05/04/2016 (BTC199571) E	
Status:	HPRA approved	
Pack Details:	White 250 micron PVC/60 gsm PVC/220 micron hard temper aluminium foil	
Pack Size:	16 Et 24	
Version No.	Date Issued	Reason For Change
1	27/04/2016	HPRA approval of an update to include PRAC recommended text and removal of the mifepristone statement.

ARTWORK TEXT SIZE		
Main Headings:	11pt	
Sub Headings:	10pt	
Body Copy:	9pt	

**TECHNICAL INFO: PRINTER PLEASE NOTE**  
Trident have created this artwork to a generic print process specification and repro has not been applied. Please call your Boots contact to discuss any amends or if anything falls beneath your print tolerances.

ARTWORK ONLY

Trident Reference No: <b>BTC199571</b>	
Zen Ref:	TR1023404
Category:	Healthcare
Sub-Category:	Analgesics
Brand:	Premium
Pack Type:	Leaflet
Variant:	Ibuprofen and Codeine 200 mg/12.8 mg Film Coated Tablets ROI – Custom
Action:	<b>G</b>
Date:	10/05/16
Country:	ROI
Component Code:	<b>PM/20/548</b>
Item Code:	<b>N/A</b>
CAD Ref No:	170 mm width x 350 mm height
Printer:	N/A
Substrate:	White Paper
Barcode Type:	N/A
Barcode Number:	N/A
Magnification:	N/A
Barcode Truncated By:	N/A
(smallest box)	
Edgemark Position:	N/A
Pharmacode No/NE:	000101(68)

Technical Et Non Printing Items

✂ Cutter      📏 Guides

Colours

PANTONE 280 C	
1	



TRIDENT

Connaught House, Connaught Road,  
Kingswood Business Park, Hull, HU7 3AP, England.  
T: +44 (0) 1482 828100

Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

**STUDIO USE ONLY** Evita Lauka v1.0  
Sm•Art check results: G=1; O=1; R=0; -EL= 10/05/16 12:45:56