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Information for the user

Boots Paracetamol & Codeine 500mg/12.8mg Tablets

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.

- This medicine can only be used for the short term treatment of acute moderate pain such as headache, migraine, period pain, backache, sciatica, dental pain, sprains and strains, arthritic and rheumatic pain that is not relieved by aspirin, ibuprofen or paracetamol alone
- This medicine is for the short term treatment of acute moderate pain when other painkillers have not worked
- **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
- 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 must talk to a doctor if you do not feel better or if you feel worse

What this medicine is for

This medicine can be used in adults and children aged 12 years and over for the short term treatment of acute moderate pain that is not relieved by aspirin, ibuprofen or paracetamol alone.

It can be used for headache, migraine, period pain, backache, dental pain, sprains and strains, sciatica, arthritic and rheumatic pain.

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

This medicine also contains paracetamol. Paracetamol, an analgesic, acts to relieve pain.

Before you take this medicine

- **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
- This medicine can be taken by adults and children aged 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:**
- **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 are allergic** to any of the ingredients
- **If you are taking** other medicines containing paracetamol or codeine
- **If you are breastfeeding** (see "Other important information")
- **If you have** respiratory depression, raised intracranial pressure or chronic constipation
- Do not give to children under 12 years.

Warnings and precautions

Tolerance, dependence, and addiction

This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.

Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Paracetamol and Codeine 500mg/12.8mg Tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

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 Paracetamol and Codeine 500mg/12.8mg 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 Paracetamol and Codeine 500mg/12.8mg Tablets, it could be a sign that you have become dependent or addicted:
- You need to take the 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 'Possible withdrawal effects when stopping treatment').

! Talk to your pharmacist or doctor:

- If you are elderly
- If you have kidney problems
- If you have liver problems (including a disease caused by drinking alcohol)
- If you have bowel problems including blockage of your bowel
- If you have had an operation to remove your gall bladder
- **If you are pregnant**
- If you have hypotension (low blood pressure) or underactive thyroid (hypothyroidism)
- If you have experienced a recent head injury
- If you have a condition called myasthenia gravis which weakens the muscles
- If you have prostate problems
- If you have Addison's disease
- If you are taking monoamine oxidase inhibitors (for depression), or have taken them in the last 14 days.

During treatment with this medicine, tell your doctor straight away if you:

- have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic).
- A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).
- have some or all of the following symptoms: mental disorder, nausea, fever, fast heart beat and muscle disorder. These may be symptoms of a condition called serotonin syndrome, which has been reported in patients taking opioids such as codeine-containing medicines, particularly with concomitant use of certain antidepressants such as tricyclic agents, selective serotonin reuptake inhibitors (SSRIs), or serotonin and norepinephrine reuptake inhibitors (SNRIs).

Other important information

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine. Alcohol increases the risk of side effects occurring and may make you feel more drowsy.

Contact your doctor if you experience:

- severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system
- pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

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.

Sleep-related breathing disorders

Paracetamol and Codeine 500mg/12.8mg Tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (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.

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.



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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.

Breastfeeding:

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

Driving and using machines:

This medicine can affect your ability to drive or use machines as it may make you feel sleepy or dizzy.

- Do not drive or use machines while taking this medicine until you are sure you are not affected
- It is an offence to drive if this medicine affects your ability to drive
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Information about some of the ingredients in this medicine:

Sodium metabisulphite (E223) may rarely cause severe allergic reactions, tightness of the chest or difficulty in breathing. This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

If you take other medicines

Do not take anything else containing paracetamol or codeine while taking this medicine.

Before you take these tablets, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Domperidone or metoclopramide for feeling sick or being sick
 - Colestyramine for lowering blood fat levels
 - Warfarin or other coumarins for thinning the blood – if you take warfarin you can take occasional doses of this medicine, but talk to your doctor first before you take it on a regular basis
 - Sleeping tablets, sedatives including benzodiazepines, tricyclic antidepressants or antipsychotics including phenothiazine
 - Monoamine oxidase inhibitors for depression
 - Sedatives to treat depression (e.g. selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs))
 - Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)
 - Medicines for epilepsy
 - Muscle relaxants
 - Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 'Before you take this medicine').
- If you are going to have a general anaesthetic, tell your doctor that you are taking this medicine. If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

✓ How to take this medicine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Check the foil is not broken before first use. If it is, do not take that tablet.

Age	How many to take	How often to take
Adults	Two	Up to 4 times a day but not more often than every 4 hours. Don't take more than 8 tablets in any 24 hours.
Children: 16 to 18 years of age	One to two	Up to 4 times a day but not more often than every 6 hours. Don't take more than 8 tablets in any 24 hours.
Children: 12 to 15 years of age	One	Up to 4 times a day but not more often than every 6 hours. Don't take more than 4 tablets in any 24 hours.

For the elderly, a reduced dose or dosing less often may be required.

Swallow each tablet whole with water.

Do not take for more than 3 days.

Paracetamol and Codeine 500mg/12.8mg Tablets should be used for 3 days only to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a healthcare professional.

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

Do not take more medicine than the table tells you to.

If you do not get better, talk to your doctor.

If your symptoms continue or your headache becomes persistent, see your doctor.

! If you take too many tablets:

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Go to your nearest hospital casualty department. 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 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:

- Difficulty in breathing, swelling of the face, neck, tongue or throat or shortness of breath (severe allergic reactions)
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin
- Very rare cases of serious skin reactions have been reported. This may include peeling, blistering and lesions of the skin
- Severe abdominal pain, nausea and vomiting if you have recently had your gall bladder removed
- Unexpected bruising or bleeding
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin
- Confusion
- Sleepiness
- Small pupils
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 'Before you take this medicine'). The frequency of this side effect is not known (frequency cannot be estimated from the available data).
- **Other possible side effects:**
- **Not known** (frequency cannot be estimated from the available data):
- Constipation
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

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 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.

! 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

Keep this medicine out of the sight and reach of children.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them. Store in the original package. Use by the date on the end flap of the carton.

What is in this medicine

Each tablet contains Codeine Phosphate Hemihydrate 12.8mg, Paracetamol 500mg, which are the active ingredients.

As well as the active ingredients, the tablets also contain maize starch, microcrystalline cellulose, magnesium stearate, sodium metabisulphite (E223).

This pack contains 24 or 30 white, pillow shaped tablets, with the letter 'M' on one side. Not all pack sizes may be marketed.

Who makes this medicine

Manufactured for the Marketing Authorisation holder
The Boots Company PLC Nottingham NG2 3AA
by Famar AVE Anthoussa Attiki 15349 Greece.

Leaflet prepared August 2026.

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

Other formats

To 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: Paracetamol and Codeine

500mg/12.8mg Tablets

Reference number: 00014/0865

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

