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PIL1862

Information for the user**Paracetamol & Codeine Extra Capsules
(Caffeine, Codeine Phosphate, Paracetamol)****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 headache, migraine, rheumatic pain, muscular pain, backache, neuralgia, toothache and period pain that is not relieved by aspirin, ibuprofen or paracetamol alone
- 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 headache, 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 Paracetamol and Caffeine. Paracetamol, an analgesic, acts to relieve pain. Caffeine helps to increase the pain relief.

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
 - This medicine contains paracetamol.** Do not take anything else containing paracetamol while taking this medicine
 - 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.

Do not take:

- If you are under 12 years**
- 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 ever had an allergic reaction** to paracetamol, caffeine, codeine, other opioid painkillers or to any of the other ingredients
- If you are taking other medicines containing paracetamol or codeine**
- If you have respiratory depression or chronic constipation**
- If you are pregnant or breastfeeding** (see "Other important information").

! Talk to your pharmacist or doctor before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more of this medicine to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it
- have kidney problems
- have liver problems (including a disease caused by drinking alcohol)
- have bowel problems, including blockage of your bowel
- have had an operation to remove your gall bladder
- have hypotension (low blood pressure) or underactive thyroid (hypothyroidism)

- have experienced a recent head injury or raised intracranial pressure
- have asthma and have been told by your doctor that you are sensitive to aspirin
- have Gilbert's Syndrome (familial non-haemolytic jaundice)
- are taking other medicines that can affect liver function
- have glucose-6-phosphatase dehydrogenase deficiency
- have haemolytic anaemia
- have glutathione deficiency
- are dehydrated
- have a poor diet such that the diet causes health problems
- weigh less than 50kg
- are elderly
- have a condition called myasthenia gravis which weakens the muscles
- 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).

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.

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.

Pregnancy and Breastfeeding: Do not take this medicine if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use this medicine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take this medicine while you are breastfeeding. Codeine and morphine passes into breast milk and will affect your baby.

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 taken to treat a medical or dental problem and
 - You have taken it according to 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.

Important information about some of the ingredients in this medicine: The colour ponceau 4R (E124) in this medicine may cause allergic reactions.

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

If you take other medicines

This medicine contains paracetamol.

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

Before you take these capsules, 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 (may increase the pain relief effect of paracetamol)
- Colestyramine for reducing blood fat levels (may reduce the pain relief effect of paracetamol)
- Monoamine oxidase inhibitors (MAOIs) for depression in the last 2 weeks or substances that make you **drowsy** (e.g. sedatives, antidepressants or alcohol) or **sedated** (e.g. benzodiazepines or related medicines)
- Warfarin or other blood thinners - if you take warfarin you can take occasional amounts of this medicine, but talk to your doctor first before you take it on a regular basis
- Medicines for epilepsy
- Probenecid for gout and hyperuricemia
- 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')
- Pregabalin and gabapentin due to an increased risk of respiratory depression.

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

Check the foil is not broken before use.

If it is, do not take that capsule.

Adults: Take two capsules every 4 – 6 hours, if you need to, up to 4 times in 24 hours.

Don't take more than 8 capsules in 24 hours. A reduced maximum daily dose should be considered if you are underweight (under 50kg). For the elderly a reduced dose may be required.

Children aged 16-18 years: Take one or two capsules every 6 hours, if you need to. Do not take more frequently than every 6 hours. **Don't take more than 8 capsules** in 24 hours.

Children aged 12-15 years: Take one capsule every 6 hours, if you need to. Do not take more frequently than every 6 hours. **Don't take more than 4 capsules** in 24 hours.

Swallow each capsule whole 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 medicine than the dosage information above tells you to.

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

Avoid too much caffeine in drinks like coffee and tea. High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest.

! If you take too many capsules: 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.

When taking this medicine you may experience:

- Constipation
- ! If you get any of these serious side effects, stop taking the capsules. See a doctor at once:**
 - Severe abdominal pain, dry mouth, nausea and vomiting if you have recently had your gall bladder removed
 - Nervousness, dizziness, irritability, drowsiness

or restlessness – do not drive or use machines if you feel drowsy or dizzy

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)
- Allergic reactions which may be severe such as skin rash and itching
- Very rare cases of serious skin reactions have been reported. This may include peeling, blistering and lesions of the skin; mouth ulcers; itching or sweating
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen or aspirin
- Unusual bruising or bleeding, or infections such as sore throats - this may be a sign of very rare changes in the blood
- Nausea, upset stomach, sudden weight loss, loss of appetite and yellowing of the eyes and skin
- Cloudy urine or difficulties urinating
- 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).

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 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

Taking higher doses or more frequent doses of opioids, such as codeine (an active ingredient of this medicine), may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor or pharmacist about your treatment. Please refer to 'How to take this medicine' for information on correct dosages and time intervals.

How to store this medicine

Do not store above 30°C. Store in the original package.

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 end flap of the carton.

What is in this medicine

Each capsule contains Caffeine 30 mg, Codeine Phosphate Hemihydrate 8 mg, Paracetamol 500 mg which are the active ingredients.

As well as the active ingredients, the capsules also contain sodium starch glycolate, magnesium stearate, sodium laurilsulfate. The capsule shell contains gelatin, quinoline yellow (E104), ponceau 4R (E124), titanium dioxide (E171), yellow iron oxide (E172), printing ink contains polyethylene glycol, shellac, black iron oxide (E172).

This pack contains 32 or 24 capsules.

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 Bristol Laboratories Ltd Northbridge Road Berkhamsted Herts HP4 1EG

Leaflet prepared January 2025.

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: Boots Paracetamol and Codeine Extra Capsules

Reference number: 00014/0613

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

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