



## Paracetamol & Codeine Extra (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, 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

### 1. What this medicine is for

This medicine can be used for the short term treatment of acute moderate pain such as headache, migraine, rheumatic pain, neuralgia, toothache and period pain 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.

### 2. 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 (See "What is in this medicine")
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains sorbitol)
- **If you are breastfeeding** (see "Other important information")

## ! **Talk to your pharmacist or doctor:**

- If you have severe kidney problems
- If you have severe liver problems (including a disease caused by drinking alcohol)
- If you have suffered from alcoholism, drug abuse, or dependence
- If you are on a low salt (sodium) diet (each tablet contains 362 mg of sodium, which may be harmful to you)
- If you are pregnant
- If you are taking a benzodiazepine (used for the treatment of anxiety or sleep disorders) e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam

## **Other important information**

**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.

**Drinking large amounts of** tea, coffee or cola (or other caffeine containing products) with this medicine may make you feel more tense and irritable.

Ask your doctor or pharmacist before taking codeine if you have:

- suffered from alcoholism, drug abuse, or dependence.

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.

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

## **If you take other medicines**

### ! **This medicine contains paracetamol.**

Do not take anything else containing paracetamol 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:

- Benzodiazepines – used for treating anxiety or sleep disorders
- 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)
- 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

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.

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life threatening. Because of this, you should only take these together if prescribed by your doctor. Please follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

**This medicine contains sodium and sorbitol**

**Sodium:** This medicine contains 388 mg sodium (main component of cooking/table salt) in each effervescent tablet. This is equivalent to 19.4% of the recommended maximum daily dietary intake of sodium for an adult.

**Sorbitol:** This medicine contains 50 mg sorbitol in each effervescent tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

### 3. How to take this medicine

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

Dissolve the tablets in a glass of water and then drink the solution.

Age	How many	How often
Adults over 18 years	Two dissolved in water	Every 4 to 6 hours, if you need to, up to 4 times in 24 hours. <b>Don't take more than 8 tablets in 24 hours.</b>
Children aged 16 to 18 years	One or two dissolved in water	Every 6 hours, if you need to, up to 4 times in 24 hours. <b>Don't take more than 8 tablets in 24 hours</b>
Children aged 12 years to 15 years	One dissolved in water	Every 6 hours, if you need to, up to 4 times in 24 hours. <b>Don't take more than 4 tablets in 24 hours.</b>
<b>Don't take more often than every 4 hours</b>		

**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 in the table.

If you do not get better, talk to 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.

## **4. 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 (severe allergic reactions)
- Very rare cases of serious skin reactions have been reported. This may include peeling, blistering and lesions of the skin.
- Severe stomach pain, which may reach through to the back. This may be a sign of pancreatitis, which is very rare.

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

- Constipation, feeling sick, being sick, stomach upset
- Drowsiness, dizziness, feeling light headed, headache - do not drive or use machines if you feel drowsy or dizzy
- Difficulty in passing urine
- Confusion, nervousness, irritability
- Feeling shaky or shaking, fast heart rate
- Difficulty sleeping
- Other allergic reactions (e.g. skin rash)
- Unusual bruising, or infections such as sore throats - this may be a sign of very rare changes in the blood.

### **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](http://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

## **5. How to store this medicine**

Do not store above 30°C. Store in the original package to help protect from moisture.

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.

## **6. What is in this medicine**

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

As well as the active ingredients, the tablets also contain sorbitol (E420), saccharin sodium, sodium bicarbonate, povidone, sodium laurilsulfate, citric acid anhydrous, sodium carbonate, dimeticone.

This pack contains 32 flat white tablets with bevelled edges, plain on one side, scored on the other side.

## **Who makes this medicine**

Manufactured for The Boots Company PLC Nottingham NG2 3AA by A. Nattermann & Cie. GmbH, Nattermannallee 1, 50829 Cologne, Germany.

Marketing Authorisation held by Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, UK

Leaflet prepared May 2021

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

Artwork reference: WBA1441 R0