

## Information for the user



### Paracetamol and 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")
- Do not give to children under 12 years.

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

- If you have kidney problems
- If you have other 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**

## **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.

**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, tricyclic antidepressants or phenothiazine tranquillisers
- Monoamine oxidase inhibitors for depression
- Medicines for epilepsy
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.

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 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. <b>Don't take more than 8 tablets in any 24 hours.</b>
Children: 16 to 18 years of age	One to two	Up to 4 times a day but not more often than every 6 hours. <b>Don't take more than 8 tablets in any 24 hours.</b>
Children: 12 to 15 years of age	One	Up to 4 times a day but not more often than every 6 hours. <b>Don't take more than 4 tablets in any 24 hours.</b>

Swallow each tablet 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 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

**When using this product you may experience:**

- Constipation

## **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

## **How to store this medicine**

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

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 12.8 mg, Paracetamol 500 mg, 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 December 2023.

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.

Artwork reference: 30153917