

**PATIENT INFORMATION LEAFLET**  
**PARACETAMOL, CODEINE & CAFFEINE 500mg/8mg/30mg**  
**SOLUBLE TABLETS**

The name of this medicine is Paracetamol, Codeine & Caffeine 500mg/8mg/30mg Soluble Tablets, which will be referred to as Paracetamol, Codeine & Caffeine Tablets throughout this leaflet.

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

- This medicine can only be used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone.
- You should only take this product for a maximum of three days at a time. If you need to take it for longer than three 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 three 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 three days it can make them worse.**
- Keep this leaflet. You may need to read it again.

**In this leaflet:**

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**1. WHAT PARACETAMOL, CODEINE & CAFFEINE TABLETS ARE AND WHAT THEY ARE USED FOR**

Paracetamol, Codeine & Caffeine Tablets contain the active ingredients paracetamol 500 mg, codeine phosphate hemihydrate 8 mg and caffeine 30 mg.

Paracetamol, Codeine & Caffeine Tablets are for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. They are used to relieve migraine, headache, dental pain, period pain, backache, rheumatic pain, strains and sprains, and sciatica.

**2. BEFORE YOU TAKE PARACETAMOL CODEINE & CAFFEINE TABLETS**

**This medicine contains codeine which can cause addiction if you take it continuously for more than three 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 three days it can make them worse.**

**Do not take Paracetamol, Codeine & Caffeine Tablets if you:**

- are **allergic (hypersensitive)** to **paracetamol, codeine, caffeine, other opioid painkillers** or any of the **other ingredients** in the tablets (these are listed in Section 6, Further Information).
- are **taking or have recently taken any other paracetamol or codeine containing products.**

- If you are under 12 years:
- **Not recommended for use in children under 12 years of age.**

- If you are over 12 years:
- **Co-codamol effervescent is not recommended in children and adolescents between 12 and 18 years who have breathing problems.**
- For pain relief in children and adolescents (12-18 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**

**Take special care with Paracetamol, Codeine & Caffeine Tablets**

Please see your doctor before you take Paracetamol, Codeine & Caffeine Tablets if you:

- **have severe liver or kidney disease**, including alcoholic liver disease.
- have **bowel problems** including blockage of the bowel.
- have had an **operation to remove your gall bladder.**

If your headaches become persistent, see your doctor.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Certain medicines can interfere with the effectiveness of each other. It is particularly important to tell your doctor or pharmacist before taking this medicine if you are also on:

- metoclopramide or domperidone (for sickness or stomach problems)
- colestyramine (used to treat high cholesterol)
- monoamine oxidase inhibitors (MAOIs) (used to treat depression)
- blood thinning medicines (anti coagulants) such as warfarin and you need to take a painkiller on a daily basis over a long period. However, you can take occasional doses of Paracetamol, Codeine & Caffeine Tablets.

It may still be alright for you to take Paracetamol, Codeine & Caffeine Tablets and your doctor will be able to decide what is suitable for you.

**Taking your medicine with food and drink**

Paracetamol, Codeine & Caffeine Tablets should be dissolved in at least half a glass of water and can be taken with or without a meal.

You should avoid drinking too much coffee or tea when taking these tablets.

**Fertility pregnancy and breast-feeding**

Please see your doctor before you take this medicine if you are pregnant or likely to become pregnant. Do not use whilst breast-feeding unless advised by your doctor.

Ask your doctor or pharmacist for advice before taking any medicines.

**Driving and using machinery**

The tablets may make you feel dizzy or drowsy. If affected do not drive or operate machinery.

**Important information about some of the ingredients of Paracetamol, Codeine & Caffeine Tablets**

Each of these tablets contains about 403.24 mg of **sodium** and may interfere if you are on a **low sodium diet**.

This product also contains **aspartame** (a source of phenylalanine), which should not be given to anyone with **phenylketonuria**.

**3. HOW TO TAKE PARACETAMOL, CODEINE & CAFFEINE TABLETS**

**Do not take for more than three days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.** "Do not take anything else containing paracetamol while taking this medicine"

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### **Dosage**

Adults, including the elderly and children 12 years and over:

Take 2 tablets dissolved in half a glass of water every 4 hours as required, up to a maximum of 8 tablets in any 24 hour period. Do not take more frequently than every 4 hours. Do not continue to take for more than 3 days unless instructed by your doctor. **Do not take more medicine than the label tells you too** If you do not get better, talk to your doctor".

**Not recommended for use in children under 12 years of age.**

**Not recommended in children and adolescents between 12 and 18 years who have breathing problems**

### **Method of Administration**

For oral administration only. These tablets should be dissolved in at least half a glass of water before taking them. Stir before use. The solution should be drunk immediately after preparation. These tablets are meant to be dissolved first so don't try to swallow them whole.

If symptoms persist consult your doctor.

### **If you take more Paracetamol, Codeine & Caffeine Tablets than you should**

If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**. Remember to take the pack and any remaining tablets with you.

The most common symptoms of overdose are nausea (feeling sick), vomiting (being sick) and stomach pain. You may also notice a rapid heartbeat.

### **Immediate**

**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.**

### **Withdrawal symptoms**

This medicine contains codeine and can cause addiction if you take it continuously for more than three 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.

If you have any further questions about this product ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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. Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk); alternatively you can call Freephone 0800 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.

If you get any of the following symptoms after taking these tablets, **you should contact your doctor immediately:**

- any sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.
- an acute allergic reaction (anaphylaxis) or swelling of the skin
- severe abdominal pain, nausea and vomiting if you have recently had your gall bladder removed
- unexplained bruising or bleeding
- nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin

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The following side effects have also been reported:

- constipation

**If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

### **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 dose
- 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 PARACETAMOL, CODEINE & CAFFEINE TABLETS**

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

Do not take this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

**Keep all medicines out of the sight and reach of children.**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Paracetamol, Codeine & Caffeine Tablets contain:**

The active ingredients are paracetamol, codeine phosphate hemihydrate and caffeine. Each tablet contains paracetamol 500 mg, codeine phosphate hemihydrate 8 mg and caffeine 30 mg.

The other ingredients are anhydrous citric acid, povidone, sodium hydrogen carbonate, sodium saccharin, anhydrous sodium carbonate, simeticone, polysorbate 80 and aspartame (E951).

### **What Paracetamol, Codeine & Caffeine Tablets look like and the contents of the pack:**

Paracetamol, Codeine & Caffeine Tablets are white, circular, flat bevelled effervescent tablets, which are plain on both sides.

Your medicine is available in blister packs of 16, 24 or 32 tablets.

### **Marketing Authorisation Holder:**

Fannin (UK) Limited, 42-46 Booth Drive, Park Farm South, Wellingborough, Northamptonshire, NN8 6GT, UK.

**Manufacturer responsible for batch release:** Fannin (UK) Limited, 57 High Street, Odiham, Hampshire, RG29 1LF, UK.

**This information is available in alternative formats upon request.**

This leaflet was last approved in May 2015

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