

## Information for the user



### Aspirin & Codeine Tablets B.P.

**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, toothache, rheumatic pains, neuralgia 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 16 years and over.

This medicine also contains Aspirin. Aspirin, a non-steroidal anti-inflammatory medicine (NSAID), also acts to reduce swelling (inflammation).

#### 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 of 16 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 in this medicine (see "What is in this medicine")
- **If you have ever had a bad reaction** after taking aspirin or any other non-steroidal anti-inflammatory medicines (you have had asthma, swelling of the lips or face, itchy skin or runny nose after taking them)
- **If you have a stomach ulcer**, or have had one in the past

- **If you have severe** liver, kidney or breathing problems
- **If you have a blood clotting disorder** (e.g. haemophilia)
- **If you have gout**
- **If you have a head injury** or a condition where there is a raised pressure in the head
- **If you are dependent on alcohol**
- **If you are constipated** or if your doctor has told you to avoid becoming constipated
- **If you are pregnant or breastfeeding** (see "Other important information")

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

- If you have other liver, kidney or breathing problems (see "Do not take")
- If you have asthma or allergic disease
- If you have inflammation of the bowel, or other bowel problems
- If you are elderly or if you are dehydrated
- If you have fits or epilepsy
- If you have myasthenia gravis, glucose-6-phosphate dehydrogenase deficiency or a hormone imbalance
- If you have an underactive thyroid, low blood pressure, or are in shock
- If you are a man with prostate problems

### **Other important information**

There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor.

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.

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

**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.

### If you take other medicines

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:

- Warfarin or other blood thinners
- Methotrexate (for cancer, psoriasis, rheumatic problems, Crohn's disease)
- Corticosteroids (used for many conditions such as pain, swelling, allergy, asthma, rheumatism and skin problems)
- Tablets for diabetes
- Medicines that make you sleepy or drowsy
- Medicines for mental health conditions or depression
- Mexiletine (for heart rhythm problems)
- Medicines for gout
- Metoclopramide or domperidone (for feeling sick or being sick)

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 cap seal is not broken before first use. If it is, do not take the tablets.

Age	How many	How often
Adults over 18 years	One or two tablets	Every 4 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 years to 18 years	One or two tablets	Every 6 hours, if you need to. <b>Don't take more than 8 tablets in 24 hours.</b>

Swallow each tablet 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 16 years.

Do not take more than the amount recommended above.

If symptoms do not go away talk to your doctor.

**! If you take too many tablets:** Talk to a doctor straight away. 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:**

- You are sick and it contains blood or dark particles that look like coffee grounds
- You pass blood in your stools or pass black tarry stools
- Severe stomach pain
- Rash, swelling of the face, runny nose, tight chest, wheezing (severe allergic reactions)

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

- Indigestion, feeling sick, being sick, constipation, abdominal pain or discomfort
- Increased bleeding time if you cut yourself
- Drowsiness, dizziness, restlessness, confusion, changes in mood, headache, hallucinations
- Fast, slow or irregular heartbeat, palpitations, fainting on standing up, low body temperature
- Reduced sex drive or impotence
- Dry mouth, sweating, facial flushing, difficulty in passing urine, itchy skin
- Difficulty focusing, difficulty breathing
- Water retention and worsening of existing kidney problems
- Rarely, liver problems

**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](http://www.mhra.gov.uk/yellowcard). 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**

Do not store above 25°C.

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 label edge or the end flap of the carton. After this date return any unused product to your nearest pharmacy for safe disposal.

## **What is in this medicine**

Each tablet contains Aspirin 400 mg, Codeine Phosphate 8 mg, which are the active ingredients.

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

This pack contains 32 white round tablets that have a score line on one side.

## **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.

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

## **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 Aspirin and Codeine Tablets B.P.

Reference number: 00014/0155

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

Component code