

Information for the user

Boots Paracetamol & Codeine Tablets

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, period pain and rheumatic pains including muscle pains and backache 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 contains two painkillers, Paracetamol and Codeine, which act to relieve pain.

It can be used for the short term treatment of acute moderate pain such as headache, migraine, toothache, period pain and rheumatic pains including muscle pains and backache that is not relieved by aspirin, ibuprofen or paracetamol alone.

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:

- **If you are allergic** to codeine or other similar “opioid” painkillers, paracetamol, or to any of the other ingredients in this medicine (see “What is in this medicine”)
- **If you have** difficulty breathing, or are having an asthma attack
- **If you have severe liver problems**
- **If you are dependent on alcohol**
- **If you have a head injury** or a condition where there is raised pressure to the head
- **If you are constipated**, or have any condition that may cause constipation or where constipation should be avoided such as if you have paralysis (non movement) of the bowel muscles
- **If you are having a flare up of an inflammatory bowel condition**, such as ulcerative colitis
- **If you have severe diarrhoea after taking antibiotics**
- **If you have a swollen stomach**, or if your stomach becomes swollen whilst taking this medicine
- **If you are under 12 years of age**
- **If you are pregnant**

! Talk to your pharmacist or doctor:

- If you have kidney or other liver problems (including liver problems caused by drinking alcohol)
- If you are taking monoamine oxidase inhibitors (MAOIs for depression), or have taken them in the last 14 days
- If you are addicted to drugs or other medicines, or have been in the past
- If you have asthma, or other breathing problems such as shallow breathing (also see “Do not take”)
- If you have an underactive thyroid, or feel very weak or rundown, or you are elderly
- If you have low blood pressure, or are in shock, or have a hormone imbalance
- If you are prone to experiencing fits
- If you have difficulty in passing urine, or are a man with prostate problems
- If you are breastfeeding (see “Other important information”)

Other important information

If you are having any blood tests, stomach tests, or go into hospital, tell your doctor that you are taking this medicine.

Driving and using machines: This medicine may make you feel drowsy, or may cause blurred or double vision. Do not drive or use machines until you are sure you are not affected.

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

Breastfeeding: Usually it is safe to take this medicine while breastfeeding as the levels of the active ingredients of this medicine in breast milk are too low to cause your baby any problems. However, some women who are at increased risk of developing side effects at any dose may have higher levels in their breast milk. If any of the following side effects develop in you or your baby stop taking this medicine and seek immediate medical advice; feeling sick, vomiting, constipation, decreased or lack of appetite, feeling tired or sleeping for longer than normal, and shallow or slow breathing.

Information about some of the ingredients: Ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) in this medicine may cause allergic reactions.

If you take other medicines

! This medicine contains paracetamol.

Do not take with any other paracetamol-containing products.

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:

- Diflunisal (another painkiller)
- Metoclopramide or domperidone (for feeling sick)
- Colestyramine (to reduce blood fat levels)
- Medicines to thin your blood (e.g. warfarin)
- Oral contraceptives
- Carbamazepine, phenobarbital, phenytoin or primidone (for epilepsy)
- Probenecid (for gout), isoniazid (an antibiotic), mexiletine or quinidine (for heart rhythm problems)
- Medicines for depression (tricyclic antidepressants and MAOIs), for other mental health conditions, for anxiety, or sleeping tablets
- Medicines for diarrhoea (e.g. loperamide), cimetidine (for stomach ulcers)

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 tablet.

Age	How many to take	How often to take
Adults and children of 12 years and over	One or two	Every 4 to 6 hours. Don't take more than 8 tablets in 24 hours.

If you have liver or kidney problems, or are elderly your doctor may tell you to take fewer tablets. If this applies to you follow your doctor's instructions.

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.

Do not give to children under 12 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:** Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of 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.

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: alternatively you can call Freephone 0800 100 3352 (available between 10 am – 2 pm Monday-Friday) or fill in a paper form available from your local pharmacy.

- ! **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)

These other effects are less serious. If they bother you talk to a pharmacist:

- Other allergic skin reactions such as rash, or red, raised, itchy skin
- Constipation, feeling sick, being sick
- Sweating, facial flushing
- Blurred vision, double vision, other changes in vision
- Confusion, dizziness, headache, drowsiness, vertigo
- Mood changes such as depression or feeling very happy
- Rigid muscles, uncontrolled muscle movements, hallucinations, nightmares
- Dry mouth, stomach spasms, convulsions, reduced appetite
- Low blood pressure, fast, slow or irregular heart rate, thumping or a flutter feeling in the chest
- Kidney problems, difficulty in breathing, slow or shallow breathing
- Difficulty in passing urine, increased frequency in urination (sometimes passing only small

amounts of urine), pain when passing urine, spasms in the bladder

- Inability to have or maintain an erection (in men)
- Unusual bruising, bleeding, fever, or infections such as sore throats – this may be a sign of very rare changes in the blood

If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.

! 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. 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 tablet contains Codeine Phosphate 8 mg, Paracetamol 500 mg, which are the active ingredients.

As well as the active ingredients, the tablets also contain potato starch, maize starch, talc, povidone, stearic acid, magnesium stearate, Nipasept (containing ethyl parahydroxybenzoate (E214), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216)).

The pack contains 32 white tablets, with a broken breakline on one side and AB on the other side.

Who makes this medicine

Manufactured for The Boots Company PLC Nottingham NG2 3AA by the Marketing Authorisation holder Bristol Laboratories Ltd Unit 3 Canalside Northbridge Road Berkhamsted HP4 1EG

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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 Tablets

Reference number: 17907/0162

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

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