



Patient Information Leaflet

# PARACODOL® TABLETS

Paracetamol (500mg)  
Codeine Phosphate Hemihydrate (8mg)

Please read this leaflet carefully because it contains important information for you. Keep this leaflet, you may need to read it again.

- 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.
- Anything else containing paracetamol while taking this medicine.
- If you are allergic to any of the ingredients.
- If you know that you metabolise codeine very rapidly into morphine.
- If you are breast-feeding.

### Consult your doctor before taking Paracodol Tablets if you:

- Are taking prescription medicines.
- Are taking medicines containing codeine, metoclopramide, domperidone, colestyramine, warfarin or other coumarin anticoagulants.
- Are taking medicines which affect the liver.
- Have a liver or kidney condition.
- Have high blood pressure or need a low sodium diet as each tablet contains 383mg of sodium.

### 1. What are Paracodol® Tablets for?

Paracodol Tablets can only be used in patients aged 12 years and over for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. This includes muscular and rheumatic pains, headache, migraine, neuralgia, period pain, toothache, aches and pains. This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

### 2. Before you take Paracodol® 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:

- 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.

Codeine is transformed into 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.

#### Children and adolescents (12-18 years old)

Do not use in children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome. The product is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

#### Pregnancy and breast-feeding

Consult your doctor before taking the tablets if you are pregnant or think you may be pregnant. Do not take codeine while you are breast-feeding. Codeine and morphine passes into breast milk.

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### Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
  - It may be an offence to drive when taking this medicine.
  - However, you would not be committing an offence if:
    - The medicine has been taken to treat a medical or dental problem and
    - You have taken it according to 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.

Details regarding a new UK driving offence concerning driving after taking drugs may be found at: [www.gov.uk/drug-driving-law](http://www.gov.uk/drug-driving-law).

### Paracodol Tablets contain sodium

This medicine contains 383 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 19.15% of the recommended maximum daily dietary intake of sodium for an adult.

### 3. How should I take Paracodol® Tablets?

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

Dissolve the tablets in water before taking.

**Adults aged 18 years and over:** Take 1-2 tablets, repeated if necessary every 4-6 hours with a maximum of 8 tablets a day. **Children aged 12 -18 years:** Take 1 tablet, repeated if necessary every 4-6 hours with a maximum of 4 tablets a day. Paracodol Tablets should not be taken by children under 12 years due to the risk of severe breathing problems.

Do not drink alcohol whilst taking this medicine.

### Withdrawal – when you stop taking Paracodol Tablets:

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.

### What if I take too many Paracodol 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.

### 4. Do Paracodol® Tablets cause any side effects?

Some people may have side-effects when taking this medicine.

### Potential side-effects

Side effects are rare, but occasionally Paracodol Tablets can cause constipation and hypersensitivity reactions such as skin rashes. Very rare cases of serious skin reactions have been reported. If you notice that you bruise or bleed more easily than usual or if you are more prone to infection, such as sore throats or mouth ulcers, you should speak to your 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) 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 dose.
- When you stop taking the medicine you feel very unwell but you feel better if you start taking the medicine again.

### 5. How should I store Paracodol® Tablets?

Keep out of the sight and reach of children. Store in the original package in order to protect from moisture. Do not use the tablets after the expiry date on the carton and blister.

### 6. Further Information

#### What do Paracodol Tablets contain?

Each effervescent tablet contains the active ingredients: paracetamol 500 mg and codeine phosphate hemihydrate 8 mg.

Inactive ingredients: povidone, sodium hydrogen carbonate, anhydrous sodium carbonate, anhydrous citric acid, mannitol, saccharin sodium, sodium docusate, sodium benzoate.

Available in packs of 16 and 32 effervescent tablets. Not all pack sizes may be marketed.

#### Who makes Paracodol Tablets?

Manufactured by Delpharm Gaillard, 74240 Gaillard, France for the Product Licence holder, Bayer plc, 400 South Oak Way, Reading, RG2 6AD, UK

Leaflet last revised: October 2019

PARACODOL® is a registered trademark.

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