

PARAMOL[®]

TABLETS

Paracetamol 500mg and Dihydrocodeine Tartarate 7.46mg

- This medicine can only be used for the short term treatment of acute moderate pain when other pain killers have not worked.
- 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 dihydrocodeine 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.

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 or pharmacist have told you.

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Paramol is and what it is used for
2. What you need to know before you take Paramol
3. How to take Paramol
4. Possible side effects
5. How to store Paramol
6. Contents of the pack and other information

1. What Paramol is and what it is used for

Paramol tablets contain the active ingredients paracetamol and dihydrocodeine. They are used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen and aspirin alone such as headache, migraine, period pain, toothache and other dental pain, backache, muscular and joint aches and pains and neuralgia. Paramol Tablets are used for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen and aspirin alone such as headache, migraine, period pain, toothache and other dental pain, backache, muscular and joint aches and pains and neuralgia.

2. What you need to know before you take Paramol

- **This medicine contains dihydrocodeine 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 pain killer for headaches for more than three days** it can make them worse.

Do not take Paramol Tablets if you:

- are allergic to paracetamol, dihydrocodeine or any of the other ingredients in the product (see section 6)
- are suffering from diarrhoea caused by poisoning or have watery and severe diarrhoea which may be bloody, especially if you have been taking antibiotics (Pseudomembranous colitis)
- are dependent on alcohol
- suffer from raised pressure within your head or from convulsion and acute abdominal conditions
- are taking antidepressants from a group called Monoamine Oxidase Inhibitors (MAOIs) or have taken them in the last 14 days
- are pregnant or breastfeeding
- are suffering from breathing difficulties
- suffer from delayed stomach emptying and decreased movement in your intestines
- are under 18 years of age and have had your tonsils or adenoids removed for Obstructive Sleep Apnoea Syndrome
- know that you metabolise codeine into morphine very rapidly

Speak to your doctor or pharmacist if you...

- have allergies
- have asthma (do not take the tablets if you are having an asthma attack)
- have liver or kidney problems
- have an underactive thyroid gland
- have low blood pressure or if your adrenal glands are not working properly
- have an enlarged prostate, bowel problems, have had recent surgery, have gallstones, difficulty passing urine
- have myasthenia gravis, a history of arrhythmias, a history of convulsions
- have a history of drug use or mood swings
- are elderly
- before giving to a child with any sort of breathing problem

Taking other medicines

- Monoamine oxidase inhibitors e.g. Pethidine, warfarin (to thin the blood), domperidone or metoclopramide (to treat nausea and vomiting), cholestyramine (to reduce cholesterol)
- Hydroxyzine (to treat anxiety), central nervous system depressants such as alcohol, anaesthetics, hypnotics and sedatives
- Phenothiazine (an antipsychotic), diuretics and medicines taken to reduce high blood pressure
- loperamide or kaolin (to treat diarrhoea)
- a drug from the antimuscarinic family (a type of drug that temporarily block nerve endings) e.g. atropine or any other kind of neuromuscular blocking medication (e.g. tracrrium)
- quinidine (to treat malaria), mexiletine (to treat high blood pressure or irregular heartbeat), cisapride and cimetidine (to treat reflux)
- naloxone (used to treat addiction to opioids) or naltrexone (a drug used to treat alcohol addiction).
- benzodiazepines (to treat depression, anxiety) or related sedative medicines.
- **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.

Take special care

- If you take a painkiller for headaches for more than three days it can make them worse.

Other medicines and Paramol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Concomitant use of Paramol and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) or sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Paramol together with opioids or sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all opioid or sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If you are pregnant or breast feeding...

- do not use this product if you are pregnant or breast feeding.

Driving and using machines

These tablets can impair mental function and can cause blurred or double vision, hallucinations, convulsions, confusion, drowsiness, dizziness and may make you sleepy.

- Do not drive while taking this medicine until you know how it affects you



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- If you feel affected, do not drive or operate machinery
- 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 driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>

3. How to take Paramol

Paramol Tablets should be taken during or after meals.

Adults and adolescents 16 years old and over:

- Take one or two tablets every four to six hours.
- Do not take more than 8 tablets in any 24 hour period.

Adolescents 12–15 years old:

- Take one tablet every four to six hours.
- Do not take more than 4 tablets in any 24 hour period.

Children under 12 years:

- Not recommended for children under 12 years.
- Take care when increasing the dose in the elderly.

If symptoms persist or worsen, consult your doctor or pharmacist.

Do not take this medicine for more than 3 days continuously without medical review.

If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.

This medicine contains dihydrocodeine 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 take too many of the 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking the medicine and seek immediate medical help if you develop any of the following

- signs of a serious allergic reaction, such as difficulties in breathing, faster heart beat, severe forms of skin reactions such as itchiness, skin rash with redness, peeling, flaking or blistering, swelling of the face.

Tell your doctor if you experience the following side effects:

- blood disorder resulting in unexplained or unusual bruising or bleeding, fever, sore throat, mouth ulcers.
- depression, hallucination, confused, changes in mood, restlessness or nightmares
- dizziness, spinning sensation, drowsiness, convulsions, uncontrollable twitching or jerking movements, headaches
- blurred vision, double vision, reduction in pupil size
- slow heartbeat, shortness of breath, cough suppression
- stomach pain, feeling sick, constipation, vomiting, dry mouth, loss of bladder control, diarrhoea
- muscle stiffness
- pain or difficulty in passing urine
- loss of libido, reduction in body temperature, excess sweating, tiredness, feeling unwell.

How do I know if I'm 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.

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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Paramol

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use after the expiry date shown on the carton and blister pack.
- If you find that you still have this medicine after its expiry date, return it to your local pharmacist who will dispose of it properly.

6. Contents of the pack and other information

Paramol Tablets contain 500mg of the active ingredient paracetamol and 7.46mg of the active ingredient dihydrocodeine tartarate. Paracetamol acts as an analgesic (pain killer) and antipyretic (lowers body temperature). Dihydrocodeine tartarate is also a powerful analgesic. They also contain magnesium stearate, maize starch, povidone, hypromellose, titanium dioxide and macrogol 400. Paramol Tablets are smooth, white caplet shaped tablets, embossed with Paramol, with a break line on the underside. They are available in blister packs containing 12, 24, or 32 tablets.

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