PARAMOL®
TABLETS

Paracetamol 500 mg and Dihydrocodeine Tartrate 7.46 mg

- 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
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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.

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) or respiratory problems
- have liver or kidney problems
- have an underactive thyroid gland
- have low blood pressure or if your adrenal glands are not working properly
- have a head injury
- have an enlarged prostate, bowel problems, have had recent surgery, have gallstones, difficulty passing urine
- have myasthenia gravis, a history of arrythmias, a history of convulsions
- have a history of drug use with mood swings or in acute alcoholism
- are elderly
- have issues with breathing during sleep (central sleep apnoea)
- have an abnormally increased sensitivity to pain (hyperalgesia)
- have issues with your liver, gallbladder, or bile ducts (hepatobiliary disorders)
- before giving to a child with any sort of breathing problem

During treatment with Paramol, tell your doctor straight away if:

If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Taking other medicines

- Monoamine oxidase inhibitors e.g. moclebemide, if used within 14 days as it may cause nervous system excitation or depression. Anticoagulats e.g. warfarin (to thin the blood), as it may increase the risk of bleeding. Antiemetics e.g. domperidone or metoclopramide (to treat nausea and vomiting). Cholerstyramine (to reduce cholesterol).
- Isoniazid (medicine used to treat tuberculosis), it may increase side effects of paracetamol.
- Medicines used to treat epilepsy (phenytoin and carbamazepine), medicines used to treat sleeping problems (barbiturates such as pentobarbital, phenobarbital), as they may increase side effects on liver.
- Hydroxyzine (to treat anxiety), central nervous system depressants such as alcohol, aneasthetics, 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. tracrium)
- Medicines used to treat overactive bladder (such as oxybutynin, hyoscyamine, atropine, benztropine)- this may increase the risk of severe constipation, slowing or stopping of intestinal movement and difficulty in passing urine.
- quinidine (to treat malaria), mexiletine (to treat high blood pressure or irregular heartbeat), cisapride and cimetidine (to treat reflux)
- Abiraterone (medicine used to treat prostate cancer) as it may decrease pain relieving effect of dihydrocodeine.
- 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.
- Medicines used to treat depression selective serotonin-reuptake inhibitors (SSRIs) (such as citalopram and escitalopram), selective serotonin- and norepinephrine-reuptake inhibitors (SNRIs) (such as venlafaxine and duloxetine), and tricyclic antidepressants (such as amitriptyline and desipramine), as they may cause a serious reaction called serotonin syndrome.
- **flucloxacillin** (antibiotic), due to a serious risk of blood and fluid abnormality (called high anion gap metabolic acidosis) that must have urgent treatment

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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 breastfeeding...

- do not use this product if you are pregnant or breastfeeding

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
- 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. Overdose can also lead to coagulation disorders which can result in excessive blood clotting or bleeding.

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 heartbeat, 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
- very rare cases of serious skin reactions have been reported
- pain or difficulty in passing urine
- loss of libido, reduction in body temperature, excess sweating, tiredness, feeling unwell.
- loss of appetite

Frequency "Not known'' (frequency cannot be estimated from the available data):

- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

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. 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.

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 500 mg of the active ingredient paracetamol and 7.46 mg of the active ingredient dihydrocodeine tartrate. Paracetamol acts as an analgesic (pain killer) and antipyretic (lowers body temperature). Dihydrocodeine tartrate 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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