

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.

What are these tablets used for?

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.

Before taking these tablets

- **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 any of the ingredient in this product. See 'What these tablets contain' for the full list of ingredients.
- If you are suffering from breathing difficulties.
- If you are taking antidepressants from a group called Monoamine Oxidase inhibitors (MAOIs) or have taken them in the last 14 days
- If you are dependent on alcohol
- If you suffer from raised pressure within your head or from convulsion and acute abdominal conditions.
- If you 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).
- With any other paracetamol and/or codeine-containing products

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 blood pressure problems or irregular heart beats • Have had recent gastrointestinal surgery
- Are elderly. • Suffer from kidney or liver problems, including non-cirrhotic alcoholic liver disease, or if you have an underactive thyroid gland, prostate problems, gallstones, difficulties passing urine or bowel problems. • Have been diagnosed with one of the following condition: rapid opioid metabolism, Addison's disease, or myasthenia gravis. • Have a history of mood swings or drug abuse

Taking other medicines

Before taking this product speak to your doctor or pharmacist if you are taking:

- domperidone or metoclopramide (to treat nausea and vomiting), loperamide or kaolin (to treat diarrhoea), cholestyramine (to reduce cholesterol), or any medication to thin the blood (e.g. warfarin, and medicines to treat high blood pressure (e.g. diuretics, known as water drugs and other antihypertensives).
- Cimetidine (an antacid to control stomach reflux), quinidine (a drug to treat malaria), cisapride (a drug to treat reflux), naloxone (a drug used to treat addiction to opioids) or naltrexone (a drug used to treat alcohol addiction)
- any treatment against anxiety (e.g. hydroxyzine), depression (e.g. tricyclic antidepressants like amitriptyline), psychological disorder (e.g. barbiturates such as barbital and CNS depressants like valium) or sleep disorder (hypnotics and sedatives like zopiclone)
- a treatment to lower your blood pressure or to correct irregular heartbeat (e.g. mexiletine),
- a drug from the antimuscarinic family (a type of drugs that temporarily block nerve endings) e.g. atropine, or any other kind of neuromuscular medication (e.g. tracrrium)

Take special care...

- If you take a painkiller for headaches for more than three days it can make them worse.
- If you need to use this medicine for more than three days at a time, see your doctor, pharmacist or healthcare professional.

- Avoid alcohol whilst taking Paramol Tablets.

If you are pregnant or breast feeding...

- Paramol Tablets are not recommended for use during pregnancy or whilst 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>

How to take these tablets

Paramol Tablets should be taken during or after meals.

Adults and children 12 years and over:

- Take one or two tablets every four to six hours.
- Do not take more than eight tablets in any 24 hour period.
- Do not exceed the stated dose.

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 for more than 3 days. If you need to use this medicine for more than three days you must speak to your doctor or pharmacist.

Possible withdrawal effects

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.

Possible side effects

Important: 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 the following side effects, stop taking the medicine and seek medical attention immediately as you may be allergic to Paramol: skin rash, itching, difficult breathing, swelling of the face.
- There have been rare reports of blood disorders, but these were not necessarily causally related to paracetamol.

Possible symptoms might include unexplained bruising or bleeding, sore throat or fever.

- Constipation, if it occurs, is readily treated with a mild laxative. Drowsiness may occur.
- Very rare cases of serious skin reactions have been reported.

Other very rare side effects may include: nausea, vomiting, sweating, facial flushing, dry mouth, blurred or double vision, headache, feeling faint or unwell, vertigo (sensation of motion either of the person or the environment), tiredness, low blood pressure whilst standing, slow heart beat or being aware of it, palpitations, very slow or shallow breathing, difficulties in passing urine, fits, hallucinations, nightmares, stiffness, depression, reduced libido or potency, hypothermia, restlessness, change of mood, liver spasm, bladder spasm, tachycardia and miosis, diarrhoea and stomach cramps.

If you feel any of the above effects or if you feel that you are reacting badly to this medicine in any way stop taking the tablets and tell your doctor or pharmacist.

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.

How to store these tablets

- 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.

What these tablets contain

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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