

P A R A M O L
1 0 M G / CHILDREN STRIKE
5 0 0 M G
T A B L E T S

Each tablet contains:
10mg dihydrocodeine hydrogen tartrate and 500mg paracetamol.
For oral administration.
Dosage: Take as directed by the doctor. Do not take more than 2 tablets at any one time. Do not take more than 8 tablets in 24 hours.
Children under 12 years: Not recommended.
Do not store above 25°C.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

10mg/500mg 100 tablets
Paramol®

10mg/500mg
TABLETS

Dihydrocodeine hydrogen tartrate/Paracetamol

CONTAINS PARACETAMOL

Do not take any other paracetamol-containing products. Immediate medical advice should be sought in the event of overdose even if you feel well. Please read the enclosed leaflet carefully.

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Do not exceed the stated dose. If symptoms persist consult your doctor. Prolonged use except on the doctor's advice may be harmful. This product should be used only when clearly necessary.

MA Holder:
Galen Limited,
Craigavon,
BT63 5UA, UK.
PA 1329/6/1

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POM



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PACKAGE LEAFLET: INFORMATION FOR THE USER
Paramol 10mg/500mg Tablets
(Dihydrocodeine Hydrogen Tartrate and Paracetamol)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Paramol 10mg/500mg Tablets are and what they are used for
2. Before you take Paramol 10mg/500mg Tablets
3. How to take Paramol 10mg/500mg Tablets
4. Possible side effects
5. How to store Paramol 10mg/500mg Tablets
6. Further information

1. WHAT PARAMOL 10mg/500mg TABLETS ARE AND WHAT THEY ARE USED FOR

Paramol 10mg/500mg Tablets are one of a group of medicines known as analgesics or painkillers. They are used to relieve moderate pain. They can also be used in the treatment of a raised temperature and dry (non-productive) cough.

2. BEFORE YOU TAKE PARAMOL 10mg/500mg TABLETS

Do not take Paramol 10mg/500mg Tablets if you

- are allergic (hypersensitive) to paracetamol, dihydrocodeine, or any of the other ingredients (see Section 6 for a full list of ingredients)
- have a condition where you breathe more slowly and weakly than expected (respiratory depression) or where you have difficulty breathing (obstructive airways disease)
- are pregnant, planning to become pregnant or breast-feeding

Check with your doctor or pharmacist before taking Paramol 10mg/500mg Tablets if you

- suffer from asthma or other allergic (hypersensitive) disorders

- are elderly and/or in poor health
- have an under active thyroid gland (hypothyroidism)
- have kidney or liver problems
- have suffered a head injury or have raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)

If any of the above apply to you, it is important that you tell your doctor or pharmacist before taking Paramol 10mg/500mg Tablets and they will decide what to do. It may still be safe for you to take Paramol 10mg/500mg Tablets.

Tolerance, Dependence and Withdrawal

Paramol 10mg/500mg Tablets may lead to physical and psychological addiction, which may result in withdrawal symptoms once the drug is stopped (See Section 3 for withdrawal symptoms). When Paramol 10mg/500mg Tablets are taken for a long time, their effects may decrease, so that higher doses have to be taken (tolerance development). Please inform your doctor if one of these problems occurs during Paramol 10mg/500mg Tablets treatment or if they have happened to you in the past.

Warnings and precautions

There are similarities to the way the body treats both dihydrocodeine and codeine. Both are transformed to a morphine derivative 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 taking codeine, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people taking codeine are more likely to get serious side effects because a very high amount of morphine is produced. The clinical implications of the variation of this enzyme is not fully clear for people taking dihydrocodeine, however, 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines, including those medicines obtained without a prescription: cough/cold remedies or other painkillers and medicines that you have bought

- yourself (note: many of these will contain dihydrocodeine and/or paracetamol and should not be taken while you are taking Paramol 10mg/500mg Tablets)
- monoamine oxidase inhibitor (MAOI) antidepressants (examples include moclobemide and tranylcypromide) or if you have taken this medicine in the last two weeks
- domperidone or metoclopramide (medicines to stop you feeling sick or vomiting)
- colestyramine (medicine for high cholesterol levels or diarrhoea)
- anticoagulants, e.g. warfarin (medicine to prevent blood clots)
- diamorphine (a very strong pain relief medicine)
- methadone (a very strong pain relief medicine, also used to treat dependence on other strong pain relief medication)
- benzodiazepines used to treat anxiety (examples include diazepam and lorazepam)
- if you have any problems with substance abuse or if you are taking or using any "drugs" such as heroin for non medical purposes

Do not take this product with any other paracetamol-containing products.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Paramol 10mg/500mg Tablets with food and drink
You should avoid alcohol when taking this product.

Pregnancy and breast-feeding

Do not take Paramol 10mg/500mg Tablets if you are pregnant, think you may be pregnant or are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

Paramol 10mg/500mg Tablets may cause drowsiness. Do not drive or use machines until you know how they affect you.

3. HOW TO TAKE PARAMOL 10mg/500mg TABLETS

Paramol 10mg/500mg Tablets should be taken orally (by mouth). Always take Paramol 10mg/500mg Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years
- **For moderate pain relief:** the usual dose is one to two tablets every four hours or as directed by your doctor.
- **For dry (non-productive) cough and control of a raised temperature:** the usual dose is one tablet every four hours.

Do NOT take more than 8 tablets in one 24-hour period.

Doctors sometimes prescribe different doses to this. Read the pharmacist's label, it will tell you exactly how many you should take.

Do NOT give Paramol 10mg/500mg Tablets to children under 12 years of age.

If you take more Paramol 10mg/500mg Tablets than you should

It is always important to follow the dose recommended on the label. If you take too many tablets, contact your nearest hospital casualty department or doctor immediately. This is also important if you have taken other medicines or "drugs" for non medical purposes. You should tell the doctor or the hospital staff which other medicines or other "drugs" that you have taken.

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.

If you forget to take Paramol 10mg/500mg Tablets

If you forget to take a dose and you still suffer from pain, take your dose as soon as you remember and then carry on as before. It is important that you do not take a double dose to make up for the forgotten dose.

If you stop taking Paramol 10mg/500mg Tablets

Do not stop treatment early unless told to do so by your doctor. Taking dihydrocodeine regularly can lead to addiction, which may cause you to experience withdrawal symptoms such as restlessness, nervousness, problems sleeping or

stomach problems when you stop the tablets suddenly. Talk to your doctor before you stop taking the tablets and follow their advice.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Paramol 10mg/500mg Tablets can cause side effects, although not everybody gets them.

Contact your doctor or pharmacist immediately if you experience:

- an allergic reaction: itching, skin rashes, swelling of the face, lips, tongue or throat, difficulty breathing or joint pain
- serious skin reactions (very rare cases of serious skin reactions have been reported)

Tell your doctor or pharmacist if you notice any of the following side effects:

- constipation
- headache
- feeling sick (nausea) or being sick (vomiting)
- dizziness
- drowsiness
- seeing or hearing things which are not there (hallucinations)
- confusion
- mood changes
- if you have difficulty passing urine
- slowing of your heart rate, quickening of your heart rate or an unusually strong heart beat

Lying down may help to relieve some of these side effects if you are experiencing them.

It is important that you do not take this product for any longer than your doctor thinks is necessary. There have been reports of people becoming dependent on

dihydrocodeine or experiencing withdrawal symptoms when they stop taking it. Let your doctor know if you experience any of the possible withdrawal symptoms (see Section 3 'If you stop taking Paramol 10mg/500mg Tablets').

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARAMOL 10mg/500mg TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Paramol 10mg/500mg Tablets after the expiry date, which is stated on the container. The expiry date refers to the last day of that month.

Do not use Paramol 10mg/500mg Tablets if you notice that the pack or any of the tablets are damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Paramol 10mg/500mg Tablets contain

The active substances are dihydrocodeine hydrogen tartrate and paracetamol. Each tablet contains 10mg of dihydrocodeine hydrogen tartrate and 500mg of paracetamol.

The other ingredients are microcrystalline cellulose, magnesium stearate and povidone.

What Paramol 10mg/500mg Tablets look like and the contents of the pack
Paramol 10mg/500mg Tablets are oval shaped, white uncoated tablets marked 'PARAMOL' on one side.

Paramol 10mg/500mg Tablets are available in packs of 100 or 500, from which your pharmacist will dispense the required amount.

Marketing Authorisation Holder
Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer
Almac Pharma Services Limited
Almac House
20 Seagoe Industrial Estate
Craigavon
BT63 5QD, UK

This leaflet was last revised in July 2014.

Paramol is a trademark

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10mg/500mg 100 tablets

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10mg/500mg
TABLETS
Dihydrocodeine hydrogen tartrate/Paracetamol

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Peel Here But Do Not Remove