

PACKAGE LEAFLET: INFORMATION FOR THE USER

Kapake 30mg/500mg Tablets (Codeine Phosphate 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. See section 4.

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1. What Kapake 30mg/500mg Tablets are and what they are used for
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1. WHAT KAPAKE 30mg/500mg TABLETS ARE AND WHAT THEY ARE USED FOR

Kapake 30mg/500mg Tablets are one of a group of medicines called analgesics or painkillers. They are used to relieve severe pain in adults. Kapake 30mg/500mg Tablets contain codeine, an opioid analgesic, in combination with paracetamol.

Codeine can be used in children over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

2. BEFORE YOU TAKE KAPAKE 30mg/500mg TABLETS

Do not take Kapake 30mg/500mg Tablets if you

- are allergic (hypersensitive) to codeine phosphate, paracetamol or any of the other ingredients in Kapake 30mg/500mg Tablets (for a full list of ingredients see Section 6).
- have suffered a head injury or have raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes)
- have been told by your doctor that you have a severe breathing difficulty called respiratory depression.
- are taking, or have taken in the last two weeks, medicine to relieve depression (Monoamine Oxidase Inhibitors/MAOIs). Ask your doctor or pharmacist if you are not sure what types of medicine you are taking.

- consume excessive amounts of alcohol on a regular basis.
- are pregnant or breastfeeding.
- are having (or have recently had) a severe but short-lasting asthma attack (acute asthma).
- know that you metabolise very rapidly codeine into morphine.

Talk to your doctor if any of the above apply to you.

Do NOT give this product to children under 12 years of age.

Do not use this product 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.

Warnings and precautions

Codeine is transformed to 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

Use in children and adolescents after surgery

Codeine should not be used for pain relief in children and adolescents after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Take special care with Kapake 30mg/500mg Tablets if you

- are elderly and/or in poor health
- suffer from an enlarged prostate
- suffer from any bowel problems
- suffer from Addison's disease
- suffer from any liver or kidney problems.

If any of the above apply to you, it is important that you speak to your doctor or pharmacist before taking Kapake 30mg/500mg Tablets and they will decide what to do. It may still be safe for you to take Kapake 30mg/500mg Tablets.

- Do not take for longer than directed by your prescriber.
- Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

Tolerance, Dependence and Withdrawal

Kapake 30mg/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 Kapake 30mg/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 Kapake 30mg/500mg Tablets treatment or if they have happened to you in the past.

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. This is especially important if you are taking:

- medicines called Monoamine Oxidase Inhibitors (MAOIs) used to treat depression, or have taken them in the last two weeks (see section 2 “Do not take Kapake 30mg/500mg Tablets...”). MAOIs are medicines such as moclobemide, phenelzine and tranylcypromine.
- medicines for depression, anxiety, other medicines known as tranquillisers, or hypnotics (medicines to help you sleep). You may experience more drowsiness if you take these medicines with codeine.
- colestyramine (medicine for high cholesterol levels or diarrhoea).
- domperidone or metoclopramide (medicines to stop you feeling sick or vomiting).
- anticoagulants, e.g. warfarin (medicine to prevent blood clots).
- antipsychotics (medicines used to treat mental illness).
- medicines that you have bought yourself such as cough/cold remedies or other painkillers. Many of these will contain paracetamol and/or codeine and should not be taken while you are taking Kapake 30mg/500mg Tablets.

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 Kapake 30mg/500mg Tablets with food and drink

You should avoid alcohol when taking this product.

Food has no influence on Kapake 30mg/500mg Tablets.

Pregnancy, breastfeeding and fertility

Do not use this product or any other codeine-containing products if you are pregnant.

Do not take codeine while you are breastfeeding. Codeine and morphine passes into breast milk.

Driving and using machines

Kapake 30mg/500mg Tablets may make you feel drowsy. Do not drive or use machines until you know how they affect you.

3. HOW TO TAKE KAPAKE 30mg/500mg TABLETS

Kapake 30mg/500mg Tablets should be taken orally (by mouth).

Always take Kapake 30mg/500mg Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults and the elderly is one to two tablets taken every four hours. You should not take more than eight tablets in any 24-hour period.

The dose for children aged 12 and over is one tablet taken every six hours, up to a maximum of four tablets in any 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.

Kapake 30mg/500mg Tablets should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

This medicine should only be taken when necessary. Do not take more than the stated dose and do not take for more than three days. If the pain does not improve after three days, talk to your doctor for advice.

If you take more Kapake 30mg/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.

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 Kapake 30mg/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 Kapake 30mg/500mg Tablets

Taking codeine regularly for a long time can lead to addiction, which might cause you to experience withdrawal symptoms such as restlessness and irritability 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, Kapake 30mg/500mg Tablets can cause side effects, although not everybody gets them.

The following side effects have been reported:

- dizziness or drowsiness
- feeling sick or vomiting

Lying down may relieve these effects.

- allergic reaction (skin rash, itching, swelling or shortness of breath)
 - serious skin reactions (very rare cases of serious skin reactions have been reported)
- If you experience any of these symptoms please tell your doctor or pharmacist immediately.

- low blood cell counts (platelets and white blood cells), which may cause unexplained bruising or bleeding
- slow heart beat
- constipation
- stomach pains
- sudden pain in the upper part of your abdomen, if you have previously had your gallbladder removed
- bladder problems
- light headedness
- narrowing of your pupils
- confusion or changes in your mood

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 codeine 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 Kapake 30mg/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 HPRA 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 KAPAKE 30mg/500mg TABLETS

Keep out of the reach and sight of children.

Do not use Kapake 30mg/500mg Tablets after the expiry date, which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Store this product in the original packaging below 25°C.

Do not use Kapake 30mg/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 Kapake 30mg/500mg Tablets contain

The active substances are codeine phosphate and paracetamol. Each tablet contains 30mg of codeine phosphate and 500mg of paracetamol.

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

What Kapake 30mg/500mg Tablets look like and contents of the pack

Kapake 30mg/500mg Tablets are oblong, white uncoated tablets marked “Kapake” with a scoreline on one side, the other side is plain and unmarked. The score line is present to help break the tablet for ease of swallowing, and not to divide the tablets into equal doses.

Kapake 30mg/500mg Tablets are available in packs of 2, 4, 6, 10, 20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 150, 200, 250 and 500 tablets.

Not all pack sizes may be marketed. *(Delete this section as appropriate)*

Marketing Authorisation Holder

Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer

Almac Pharma Services Limited
Almac House
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