

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 because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kapake 30mg/500mg Tablets are and what they are used for
2. What you need to know before you take Kapake 30mg/500mg Tablets
3. How to take Kapake 30mg/500mg Tablets
4. Possible side effects
5. How to store Kapake 30mg/500mg Tablets
6. Contents of the pack and other information

1. What Kapake 30mg/500mg Tablets are and what they are used for

Kapake 30mg/500mg Tablets are used to relieve severe pain in adults.

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.

This medicine contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It also contains paracetamol, another analgesic to relieve pain.

2. What you need to know before you take Kapake 30mg/500mg Tablets

Do not take Kapake 30mg/500mg Tablets:

- if you are allergic to codeine phosphate, paracetamol or any of the other ingredients of this medicine (listed in section 6).
- if you 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 you have been told by your doctor that you have a severe breathing difficulty called respiratory depression.
- if you are having (or have recently had) a severe but short-lasting asthma attack (acute asthma) or any other breathing problems, for example chronic bronchitis or emphysema.
- if you consume excessive amounts of alcohol on a regular basis.

- if you 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.
- if you are pregnant or breast-feeding.
- if you know that you metabolise very rapidly codeine into morphine.
- if you have recently had an operation on your liver, gallbladder or bile duct (biliary tract).
- if you suffer from severe kidney or severe liver disease.

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

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.

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

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.

Talk to your doctor, pharmacist or nurse before taking Kapake 30mg/500mg Tablets:

- if you are elderly and/or in poor health
- if you suffer from an enlarged prostate
- if you suffer from narrowing of your urethra (tube through which urine is passed)
- if you suffer from any bowel problems
- if you suffer from seizures (fits)
- if you have an underactive thyroid gland
- if you have a condition which weakens the muscles called myasthenia gravis
- if you suffer from Addison's disease
- if you suffer from any liver or kidney problems
- if you weigh less than 50kg
- if you suffer from chronic malnutrition or dehydration
- if you have glutathione deficiency (a metabolic disorder which may lead to difficulty in breakdown of paracetamol).

If any of the above apply to you, it is important that you speak to your doctor, pharmacist or nurse before taking this medicine and they will decide what to do. You may need to reduce the dose or avoid taking this medicinal product altogether.

- 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.

This product contains paracetamol:

- Do not take any other paracetamol-containing products
- Do not exceed the stated dose
- Immediate medical advice should be sought in the event of overdose, because of the risk of irreversible liver damage.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Kapake 30mg/500mg Tablets:

- You experience pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Sleep-related breathing disorders

Kapake 30mg/500mg Tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tolerance, dependence, and addiction

<u>This medicine contains codeine which is an opioid medicine. It can cause dependence and/or addiction.</u>
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Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Kapake 30mg/500mg Tablets can also lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Kapake 30mg/500mg Tablets if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Kapake 30mg/500mg Tablets, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose

-You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

– You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'

– You have made repeated, unsuccessful attempts to quit or control the use of the medicine

– When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Kapake 30mg/500mg Tablets).

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.

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.

Other medicines and Kapake 30mg/500mg Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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.
- sedative medicines such as benzodiazepines or related drugs, including those used for depression, anxiety, other medicines known as tranquillisers, or hypnotics (medicines to help you sleep). Taking these medicines with Kapake 30mg/500mg Tablets increases the risk of drowsiness, difficulties in breathing (respiratory depression) and 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 Kapake 30mg/500mg Tablets together with sedative medicines, the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all 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.
- medicines to help relax muscles (e.g. baclofen).

- medicines for irregular heartbeat (e.g. mexiletine, quinidine).
- fluoxetine or paroxetine (used to treat anxiety or depression).
- 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.
- domperidone or metoclopramide (medicines to stop you feeling sick or vomiting). The speed of absorption of paracetamol may be increased by these medicines.
- colestyramine (medicine for high cholesterol levels or diarrhoea). The absorption of paracetamol is reduced by this medicine.
- medicines used to treat seizures (carbamazepine, phenytoin, phenobarbital, primidone).
- rifampicin (an antibiotic used for infections).
- herbal medicines containing St John's wort.
- anticoagulants, e.g. warfarin (medicine to prevent blood clots). There may be an increased risk of bleeding caused by prolonged regular use of paracetamol.
- other strong painkillers called opioids.
- 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.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

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

Kapake 30mg/500mg Tablets with food and alcohol

You should avoid alcohol when taking this product.

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

Pregnancy and breast-feeding

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

Do not take codeine while you are breast-feeding. 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.

Kapake 30mg/500mg Tablets contain sodium

This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Kapake 30mg/500mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Kapake 30mg/500mg Tablets, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, If you stop taking Kapake 30mg/500mg Tablets).

Kapake 30mg/500mg Tablets should be used for the shortest duration necessary to relieve symptoms. If no effective pain relief is achieved while taking the medicine, you should seek the advice of a physician.

The recommended 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.

A lower dosage may be needed if you are elderly or have other medical problems. Check with your doctor about this.

Use in children and adolescents

The recommended 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.

This medicine should not be taken by children below the age of 12 years, due to the risk of severe breathing problems.

Liver or kidney impairment

If you have mild to moderate liver problems or mild to moderate kidney problems your doctor may reduce the dose of paracetamol or increase the dosing interval.

Your doctor may reduce your dose if:

- You weigh less than 50 kg
- You suffer from chronic alcoholism, malnutrition or dehydration

If you feel the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

This medicine should be taken orally (by mouth). The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

If you experience any of these symptoms, please tell your doctor or pharmacist immediately:

- allergic reaction (skin rash, itching, swelling or shortness of breath)
- serious skin reactions (very rare cases of serious skin reactions have been reported)
- sudden pain in the upper part of your abdomen, if you have previously had your gallbladder removed
- signs of bronchospasm such as difficulty in breathing, shortness of breath, wheezing, tightness in the chest (more likely to occur in those with asthma who are sensitive to medicines used to treat inflammation, such as aspirin)

The following side effects have been reported:

- dizziness or drowsiness
- feeling sick or vomiting

Lying down may relieve these effects.

- constipation
- bladder problems
- light headedness
- headache
- slow or weak breathing
- hallucination
- confusion or changes in your mood
- narrowing of your pupils
- slow heart beat
- stomach pains
- itchy skin or itchy, raised rash (hives)
- low blood cell counts (platelets and white blood cells), which may cause unexplained bruising or bleeding
- problem affecting a valve in the intestines (sphincter of Oddi dysfunction). The frequency is not known (cannot be estimated from the available data).
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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, Website: www.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 this medicine out of the sight and reach of children.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been intended for them.

Do not use this medicine 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 below 25°C. Store in the original package in order to protect from light and moisture.

Do not use this medicine if you notice that the pack or any of the tablets are damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other 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 (type A) 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.

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.

Marketing Authorisation Holder

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Manufacturer

Almac Pharma Services Limited
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20 Seagoe Industrial Estate
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Almac Pharma Services (Ireland) Limited
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