

## **Package leaflet: Information for the user**

### **Kapake 30mg/500mg Capsules** (Codeine Phosphate Hemihydrate and Paracetamol)

**This medicine contains codeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**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 Capsules are and what they are used for
2. What you need to know before you take Kapake 30mg/500mg Capsules
3. How to take Kapake 30mg/500mg Capsules
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#### **1. What Kapake 30mg/500mg Capsules are and what they are used for**

Kapake 30mg/500mg Capsules 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 has been prescribed for you for pain relief. It contains codeine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. It also contains paracetamol, another analgesic to relieve pain.

#### **2. What you need to know before you take Kapake 30mg/500mg Capsules**

##### **Do not take Kapake 30mg/500mg Capsules:**

- if you are allergic to codeine phosphate hemihydrate, paracetamol or any of the other ingredients of this medicine (listed in section 6).
- if you are suffering from increased pressure on the brain or a head injury.

- if you have been told by your doctor that you have a severe breathing difficulty called respiratory depression.
- if you suffer from severe but usually short-lasting asthma attacks (acute asthma).
- 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.

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 prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more Kapake 30mg/500mg Capsules to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Also, talk to your doctor, pharmacist or nurse before taking Kapake 30mg/500mg Capsules:

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

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. It may still be safe for you to take this medicine.

- Do not take for longer than directed by your prescriber.
- Taking a painkiller for headaches too often or for too long can make them worse.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.

### **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.

### **Other medicines and Kapake 30mg/500mg Capsules**

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 Capsules..."). MAOIs are medicines such as moclobemide, phenelzine and tranlycypromine.
- 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 Capsules 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 Capsules 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.

- 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.
- anticoagulants, e.g. warfarin (medicine to prevent blood clots). There may be an increased risk of bleeding caused by prolonged regular use of paracetamol.
- 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 Capsules.

### **Kapake 30mg/500mg Capsules with food and alcohol**

You should avoid alcohol when taking this product.

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

### **Pregnancy and breast-feeding**

Do not take Kapake 30mg/500mg Capsules if you are pregnant or think you might be pregnant.

Do not take Kapake 30mg/500mg Capsules while you are breast-feeding as codeine passes into breast milk and will affect your baby.

### **Driving and using machines**

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

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in 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.

### **Kapake 30mg/500mg Capsules contain Cochineal Red A (E124) and sodium**

Cochineal Red A (E124) may cause allergic reactions.

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

## **3. How to take Kapake 30mg/500mg Capsules**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your prescriber should have discussed with you, how long the course of Kapake 30mg/500mg Capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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

#### **Use in children and adolescents**

The recommended dose for children aged 12 and over is one capsule taken every six hours, up to a maximum of four capsules 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.

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

This medicine should be taken orally (by mouth).

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 Capsules than you should**

It is always important to follow the dose recommended on the label. Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

#### **If you forget to take Kapake 30mg/500mg Capsules**

If you forget to take a dose, it may be because your symptoms have been relieved and you may not need to take this medicine any more. However, if 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 Capsules**

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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 gall bladder removed

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
- confusion or changes in your mood
- narrowing of your pupils
- slow heart beat
- stomach pains
- itchy skin
- low blood cell counts (platelets and white blood cells) but these were not necessarily related to paracetamol
- dependence and addiction (see section “How do I know if I am addicted?”)

#### Drug Withdrawal

When you stop taking Kapake 30mg/500mg Capsules, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

#### **How do I know if I am addicted?**

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

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

#### **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 website: [www.mhra.gov.uk/yellowcard](http://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 Kapake 30mg/500mg Capsules**

Keep this medicine out of the sight and reach of children.

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.

Do not store this medicine above 30°C.

Do not use this medicine if you notice that the pack or any of the capsules 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 Capsules contain**

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

The other ingredients are sodium starch glycolate (type A) and magnesium stearate. The capsule shells are made of gelatin and contain cochineal red A (E124) (see section 2 “Kapake 30mg/500mg Capsules contain ...” for information about this ingredient), brilliant blue (E133) and titanium dioxide (E171) as colouring agents. The ink on the capsule shells contains shellac, black iron oxide (E172) and propylene glycol.

### **What Kapake 30mg/500mg Capsules look like and contents of the pack**

Kapake 30mg/500mg Capsules are hard gelatin capsules which have a red cap and a white body, printed “G 30/500” on both the cap and body.

Kapake 30mg/500mg Capsules are available in packs of 1, 2, 3, 4, 5, 6, 8, 9, 10, 12, 16, 20, 21, 24, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 200, 224, 250, 300, 400, 500 and 1000 capsules. 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  
20 Seagoe Industrial Estate  
Craigavon  
BT63 5QD  
UK

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