

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Kapake 15mg/500mg Tablets**

(Codeine Phosphate Hemihydrate 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 15mg/500mg TABLETS ARE AND WHAT THEY ARE USED FOR**

Kapake 15mg/500mg Tablets are one of a group of medicines called analgesics or painkillers. They are used to relieve moderate pain. Kapake 15mg/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 15mg/500mg TABLETS**

**Do not take Kapake 15mg/500mg Tablets if you**

- are allergic (hypersensitive) to codeine phosphate hemihydrate, paracetamol or any of the other ingredients in Kapake 15mg/500mg Tablets.
- are suffering from head injuries.
- 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 15mg/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 15mg/500mg Tablets and they will decide what to do. It may still be safe for you to take Kapake 15mg/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.

### **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 15mg/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).
- 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 15mg/500mg Tablets.

### **Taking Kapake 15mg/500mg Tablets with food and drink**

You should avoid alcohol when taking this product.

Food has no influence on Kapake 15mg/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 15mg/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 15mg/500mg TABLETS**

Kapake 15mg/500mg Tablets should be taken orally (by mouth).

Always take Kapake 15mg/500mg Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

The dose for children aged 16 and over is two tablets taken every six hours. You should not take more than eight tablets in any 24-hour period.

The dose for children aged 12 to 15 years 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 these. Read the pharmacist's label, it will tell you exactly how many you should take.

Kapake 15mg/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 15mg/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 15mg/500mg Tablets**

If you forget to take a dose, it may be because your symptoms have been relieved and you may not need to take Kapake 15mg/500mg Tablets 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 15mg/500mg Tablets**

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.

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 15mg/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) but these were not necessarily related to paracetamol
- slow heart beat
- constipation
- stomach pains
- sudden pain in the upper part of your abdomen, if you have previously had your gall bladder removed
- bladder problems
- light-headedness
- narrowing of your pupils

- confusion or changes in your mood

### **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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE KAPAKE 15mg/500mg TABLETS**

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

Do not use Kapake 15mg/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.

This medicinal product does not require any special storage conditions.

Do not use Kapake 15mg/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 15mg/500mg Tablets contain**

The active substances are codeine phosphate hemihydrate and paracetamol. Each tablet contains 15mg of codeine phosphate hemihydrate and 500mg of paracetamol.

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

### **What Kapake 15mg/500mg Tablets look like and contents of the pack**

Kapake 15mg/500mg Tablets are oblong, white uncoated tablets. One side has the markings 'K1' on both sides of a score line, the other side has no markings. The score line is present to help break the tablet for ease of swallowing, and not to divide the tablets into equal doses.

Kapake 15mg/500mg Tablets are available in packs of 4, 30 and 100 tablets. Not all of these pack sizes may be marketed.

### **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 06/2015.

The following date should be inserted below the in-house PX code on the mock-up: “03/06/15”