

PACKAGE LEAFLET: Information for the patient

KODEINE FOSFAT

Tablets – 15 mg

(Codeine phosphate hemihydrate)

Read 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 signs of illness 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 Kodeine fosfat is and what it is used for
2. Before you take Kodeine fosfat
3. How to take Kodeine fosfat
4. Possible side effects
5. How to store Kodeine fosfat
6. Other information

1. WHAT KODEINE FOSFAT IS AND WHAT IT IS USED FOR

Codeine is an opioid analgesic, which stimulates opiate receptors in the central nervous system; it also causes respiratory depression, peripheral vasodilatation, inhibition of intestinal peristalsis, stimulation of chemoreceptors that cause vomiting and inhibition of cough reflex.

Kodeine fosfat 15 mg tablets are indicated in:

- the relief of mild to moderate pain;
- the relief of dry cough (non-productive);
- simple diarrhea; it does not replace oral rehydration therapy (symptomatic treatment).

2. BEFORE YOU TAKE KODEINE FOSFAT

Do not take Kodeine fosfat:

- if you are hypersensitive to codeine, opiates or to any of the other excipients of these tablets;
- if you suffer from obstruction of the upper respiratory tract;
- if you have acute respiratory depression;
- during the acute attack of asthma;
- if you are an ultra - rapid metaboliser of codeine;
- if you have diarrhea caused by poisons or toxins;
- if you have cough with viscous secretions;
- if you have liver or kidney impairment;
- if you are at risk of paralytic ileus;
- if you are under 18 years old and have undergone the removal of tonsils for the treatment of obstructive sleep apnea;
- in case of raised intracranial pressure and head injury;
- in conditions where peristaltic inhibition should be avoided;
- in abdominal distension;
- in acute diarrhea conditions, such as ulcerative colitis or colitis associated with antibiotics;
- if you are breastfeeding.

Comatose patients should not be treated with Kodeine fosfat.

Codeine is contraindicated in children less than 12 years old and is not recommended in children and adolescents 12 - 18 years old who have breathing problems.

Long-term use should be avoided in patients with constipation.

Take special care with Kodeine fosfat

Always take Kodeine fosfat as your doctor has told you. If you are not sure, contact your doctor or pharmacist. If you feel that the effects of Kodeine fosfat are too strong or too weak, talk to your doctor or pharmacist.

Codeine should be used with caution in patients with: mixedema, impaired respiratory function, asthma, acute alcoholism, data on abusive use of narcotic drugs, ulcerative collitis, acute abdomen, urethral stenosis, hypoxia, hypotension, *Myasthenia gravis*, prostate hypertrophy, convulsions, gallstones, supraventricular tachycardia, circulatory shock.

Codeine as a narcotic analgesic, may cause tolerance and psychological and physical dependence.

The drug may harm the ability of the patient to drive and use machinery.

If you notice any of the following symptoms after you have taken codeine, stop it and call immediately the doctor: slow or not deep breathing, confusion, sleepiness, small pupils, feeling sick, constipation or lack of appetite.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Kodeine fosfat. Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Kodeine fosfat if you have been given any other drug during treatment.

It is especially important that your doctor be aware of the fact that you are treated with:

- opioid antagonists;
- general anesthetics;
- tricyclic antidepressants;
- monoamine oxidase inhibitors (MAOI);
- anxiolytics and hypnotics;
- central nervous system depressants;
- mexiletine;
- ritonavir;
- cisapride;
- domperidone and metoclopramide;
- other antidiarrheics;
- rifampicin.

The drugs that reduce the hepatic conversion of codeine into morphine, when used concomitantly, may reduce the analgesic effect of codeine. Such drugs are: quinidine, amiodarone, metoclopramide, cimetidine, neuronal serotonin reuptake inhibitors, haloperidol, propafenone and thioridazine.

The combination of codeine with verapamil may potentiate the constipant effect.

The opioid analgesics when combined with antimuscarinic drugs may cause paralytic ileus.

Taking Kodeine fosfat with food and drinks

Kodeine fosfat tablets should be taken after the meals. It should not be taken concomitantly with alcohol.

Pregnancy

Category C.

Ask for the advice of a pharmacist or doctor before taking this drug.

Codeine may cause respiratory depression in the neonate, thus its use should be carefully evaluated.

Breast feeding

Kodeine fosfat should not be taken during breast - feeding because codeine can harm the baby since it passes into breast milk.

Driving and using machines

The drug may harm the ability of the patient to drive and use machines. This effect is marked if it is accompanied with alcohol consume.

Important information about some of the excipients of Kodeine fosfat

This drug contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you take this drug.

3. HOW TO TAKE KODEINE FOSFAT

Always take Kodeine fosfat tablets as your doctor has told you. If you feel that the effects of Kodeine fosfat are too strong or too weak, talk to your doctor or pharmacist.

Dosage:

Codeine should be used in the lowest effective dose, for the shortest possible time.

As analgesic, only for the treatment of moderate, acute pain and only in cases when it is not relieved by other analgesics such as ibuprofen and paracetamol, children over 12 years old and adults: 30 - 60 mg every 4 hours up to a maximum of 240 mg daily.

For children the dose is based on body weight.

Against cough, children over 12 years old and adults: 15 - 30 mg, 3 or 4 times daily.

Generally, for the relief of cough, codeine is not recommended in children.

Against diarrhea, adults: 30 mg, 3 or 4 times daily. It is not recommended in children.

Special patients

A reduced dosage is recommended in the elderly, debilitated patients, in hypothyroidism and adrenocortical insufficiency.

If you take more Kodeine fosfat

If you take more Kodeine fosfat than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Kodeine fosfat

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

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

If you stop taking Kodeine fosfat

It should not be withdrawn abruptly after a prolonged use. Abrupt withdrawal of Kodeine fosfat from physically dependent patients, causes the withdrawal syndrome.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Kodeine fosfat may cause side effects, although not everybody manifests them. Most side effects are dose - related and disappear when the dosage is reduced or when treatment is discontinued. Some side effects may occur at the beginning of the treatment and disappear spontaneously with treatment continuance.

The side effects that may be caused by Kodeine fosfat are as follows:

- in the cardiovascular system (peripheral vasodilatation, orthostatic hypotension, bradycardia, tachycardia, palpitation, shock);
- in the central nervous system (sedation, dizziness, disorientation, drowsiness, headache, euphoria, delirium, hypothermia, mood changes, myosis, blurred vision, tremor, myoclonus, convulsions, dependence, sleep disorders);
- in the digestive tract (dry mouth, nausea, vomiting, constipation, abdominal pain, anorexia, biliary tract spasms);
- in the respiratory tract (in high doses): respiratory depression, laryngospasm;
- in the genito - urinary tract (urethral spasms, urinary retention, antidiuretic effect, reduced libido and / or sexual impotence);
- in the skin: hypersensitivity symptoms are observed, such as: pruritus, rash, sweating.

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE KODEINE FOSFAT

Keep away from children!

Do not use Kodeine fosfat after the expiry date which is stated on the package.

Store below 25°C.

Store in the original packaging to protect it from light.

6. OTHER INFORMATION

What Kodeine fosfat contains

The active substance is codeine phosphate hemihydrate.

Each tablet contains 15 mg codeine phosphate hemihydrate.

The excipients are: lactose, microcrystalline cellulose, talc, magnesium stearate.

Content of the pack:

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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