

Package leaflet: information for the patient**CODEINĂ SLAVIA 15 mg tablets**

Fosfat de codeină hemihidrat

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any additional questions, ask your physician or pharmacist.
- This medicine has been described only for you. You should not give it to other people. It can harm them, even if they present the same disease symptoms as you.
- If you experience any adverse reactions, contact your physician, pharmacist or nurse. These include any possible adverse reactions not mentioned in this leaflet. See section 4.

What is in this leaflet

1. What Codeină Slavia is and what it is used for
2. What you need to know before you use Codeină Slavia
3. How to use Codeină Slavia
4. Possible adverse reactions
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1. What Codeină Slavia 15 mg is and what it is used for

This medicine contains codeine. Codeine belongs to a class of medicines called opioid analgesics, which relieve pain through their action. It can be used alone or in combination with other analgesics, such as paracetamol.

Codeine may be used for a short period of time in adolescents over 12 years of age for the relief of moderate pain that is not relieved by other analgesics such as paracetamol or ibuprofen used alone.

In adults, adolescents and children over 12 years of age as symptomatic treatment for:

- dry irritating cough in adults;
- mild to moderate pain (usually in combination with an analgesic-antipyretic, for example paracetamol or acetylsalicylic acid);

and in adults as symptomatic treatment in:

- selected cases of diarrhoea.

2. What you need to know before you use Codeină Slavia 15 mg**Do not take Codeină Slavia 15 mg**

- for pain relief in children and adolescents (aged 0–18 years) after removal of the tonsils or adenoids (polyps) for the treatment of obstructive sleep apnoea syndrome;
- if you know that you metabolise codeine very rapidly into morphine;
- if you are allergic (hypersensitive) to codeine, to other opioids or to any of the ingredients of this medicine;
- if you have severe respiratory insufficiency, tracheobronchial hypersecretion, asthmatic cough or bronchial asthma attacks;

- if you have acute infectious diarrhoea, subocclusion or intestinal obstruction, or if you have recently undergone surgery on the biliary tract (codeine increases pressure in the biliary tract);
- if you have head injuries or other conditions associated with increased intracranial pressure;
- if you are breast-feeding;
- if the patient is a child under 6 years of age;
- if you are taking medicines called mixed opioid agonist–antagonists, such as nalbuphine, buprenorphine or pentazocine;
- if you are taking MAO inhibitors (monoamine oxidase inhibitors – medicines used to treat depression) or if less than 14 days have passed since stopping treatment with an MAO inhibitor.

Warnings and precautions

Codeine is converted into morphine by an enzyme in the liver. Morphine is the substance that provides pain relief. Some people have a variation of this enzyme and this can affect them in different ways. In some people, morphine is not produced or is produced in very small amounts, and therefore sufficient pain relief will not be obtained. Other people are more likely to experience serious side effects because very high levels of morphine are produced.

If you notice any of the following side effects, you must stop taking this medicine and seek medical advice immediately: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, or loss of appetite.

Take special care when using CODEINĂ SLAVIA 15 mg:

- if it is used in children, because codeine doses higher than 0.3 mg/kg have a convulsant potential; the risk of respiratory depression is higher;
- if you are elderly, because the risk of respiratory depression is greater and disorders such as agitation, confusion, and hallucinations occur more frequently;
- if you have a productive cough, because suppressing the cough reflex may promote the retention of tracheobronchial secretions in the airways;
- if you have impaired respiratory function, pulmonary emphysema, pulmonary fibrosis, chronic obstructive pulmonary disease (COPD), bronchorrhea, severe tuberculosis, chest trauma, or bronchial asthma;
- if you have intestinal obstructive disorders, ulcerative colitis, or have had recent gastrointestinal surgery;
- if you have infectious diarrhea;
- if it is used in children with colitis;
- if you have acute undiagnosed abdominal pain;
- if you have biliary dyskinesia or gallstones (cholelithiasis);
- if you have pancreatitis;
- if you have myasthenia gravis;
- if you have Addison's disease;
- if you have pheochromocytoma;
- if you have hypovolemia, chronic cor pulmonale, acute myocardial infarction, or shock;
- if you have cerebral edema, epilepsy, or confusional states;
- if you have hypothyroidism;
- if you have prostatic hypertrophy or urethral strictures;
- if you have hepatic or renal impairment, **as** lower doses may be required.

Other important warnings

Do not take this medicine for a longer period than recommended by your doctor.

Prolonged administration may cause dependence, which may result in restlessness and irritability when treatment with Codeină Slavia is discontinued.

Long-term use of analgesics may worsen pain.

Use of other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Contraindicated interactions

- Monoamine oxidase inhibitors (MAOIs) (medicines used to treat depression) – high toxic risk (see subsection “Do not use Codeină Slavia”).
- Morphine agonist–antagonists (nalbuphine, buprenorphine, pentazocine) – reduction of the analgesic effect.

Interactions not recommended

- Hypnotics, sedatives, tranquilizers, tricyclic antidepressants, phenothiazines, general anesthetics, sedating antihistamines and other morphine derivatives have additive effects with codeine regarding sedation and respiratory depression.
- There is a risk of increased respiratory depression when codeine is associated with ethyl alcohol. Concomitant use with alcoholic beverages increases the frequency of psychomotor impairment.
- Antibiotics (ciprofloxacin) – opioid premedication should be avoided as opioids reduce the plasma concentration of ciprofloxacin.
- Naltrexone – risk of reduced analgesic effect.
- Anticholinergics – risk of severe constipation, which may lead to paralytic ileus and/or urinary retention.

Interactions requiring caution

- Concomitant use of codeine with antihypertensive medicines increases the risk of hypotensive events.
- Concomitant use of codeine with expectorant medication may promote retention of tracheobronchial secretions.

Interactions to be taken into account

Codeine may also interact with:

- Mexiletine – delayed absorption.
- Metoclopramide, domperidone, cisapride – may counteract the gastrointestinal effects.
- Antiulcer medicines – cimetidine inhibits the metabolism of opioid analgesics.
- Antidiarrheal medicines (loperamide, kaolin) – increased risk of severe constipation.
- Quinidine – reduction of the analgesic effect.
- Antiviral medicines – ritonavir may increase plasma concentrations of codeine.

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 the tonsils or adenoids (adenoidectomy) for the treatment of obstructive sleep apnoea syndrome.

Use in children with breathing problems

Codeine is not recommended in children with breathing problems, as the symptoms of morphine toxicity may be more severe in these children.

Pregnancy and breastfeeding

Do not take codeine while breastfeeding. Codeine and morphine pass into breast milk.

Driving vehicles and using machines

Codeină Slavia may cause drowsiness, confusion or dizziness, and may cause convulsions, blurred vision or double vision. Make sure you are not affected before driving vehicles or using machines.

Important information about some ingredients of Codeină Slavia 15 mg

This medicine contains lactose.

If your doctor has told you that you have an intolerance to some sugars, ask your doctor before taking this medicine.

3. How to use Codeină Slavia

Always use this medicine exactly as your physician, pharmacist or nurse has told you. Talk to your physician, pharmacist or nurse if you are not sure.

Adults

Treatment of diarrhoea: the recommended dose is 1 tablet of Codeină Slavia 15 mg (30 mg codeine phosphate hemihydrate) 3–4 times a day.

Pain relief: the recommended dose is 2–4 tablets of Codeină Slavia 15 mg (30–60 mg codeine phosphate hemihydrate) every 6 hours, up to a maximum dose of 240 mg per day.

Treatment of cough: the recommended dose is 1–2 tablets of Codeină Slavia 15 mg (15–30 mg codeine phosphate hemihydrate) 3–4 times a day.

Adolescents aged 12 years or over: should take a dose every 6 hours, as needed. Do not take more than 240 mg in a 24-hour period.

This medicine should not be taken for more than 3 days. If the pain does not improve after 3 days, consult your doctor for advice.

Codeină Slavia 15 mg must not be given to children under 12 years of age because of the risk of severe breathing problems.

Elderly patients

In elderly patients, lower doses of codeine or longer intervals between doses may be required compared with those usually recommended for younger adults.

Patients with hepatic or renal impairment

Your doctor will recommend lower doses (see subsection “Take special care when using Codeină Slavia 15 mg”).

Codeină Slavia 15 mg may be taken with a glass of water and/or with food to reduce gastric irritation.

If you take more Codeină Slavia 15 mg than you should

If you have taken more Codeină Slavia 15 mg than the recommended dose, contact your doctor or the nearest emergency department immediately.

Symptoms of overdose (intoxication) include feeling or being sick, drowsiness, fatigue, decreased blood pressure, slowed breathing and slowed heart rate.

If you forget to take Codeină Slavia 15 mg

Do not take a double dose to make up for a forgotten dose.

If you have any further questions about this medicine, ask your doctor or pharmacist.

4. Possible adverse reactions

As any other medicine, Codeină Slavia may be associated with adverse reactions, even if they will not occur in every patient.

Adverse reactions are classified according to frequency, using the following convention:

- very common (may affect more than 1 in 10 people);
- common (may affect less than 1 in 10 people);

- uncommon (may affect less than 1 in 100 people);
- rare (may affect less than 1 in 1000 people);
- very rare (may affect less than 1 in 10000 people);
- not known (frequency cannot be estimated from the available data).

Common

- Drowsiness, mild headache
- Constipation, nausea, vomiting
- Itching, urticaria

Uncommon

- Confusion, mood changes, hallucinations, nightmares, tolerance or dependence (the risk of dependence increases with high doses administered for long periods)
- Slow heart rate, palpitations, low blood pressure
- Dizziness, vertigo, agitation
- Blurred or double vision
- Difficulty breathing with shortness of breath, respiratory depression, pulmonary oedema
- Spasms of the biliary tract, dry mouth, abdominal pain, intestinal paralysis
- Urethral spasms, urinary retention
- Temporary flushing of the face
- Unusual tiredness, general malaise, constriction of the pupils, decrease in body temperature

Rare

- Convulsions, myoclonus, increased intracranial pressure

Abrupt discontinuation of treatment may lead to withdrawal syndrome. Symptoms may include tremor, insomnia, nausea, vomiting, sweating and increased blood pressure, heart rate and respiratory rate. Tolerance decreases rapidly after a period of abstinence, so that a previously tolerated dose may become lethal.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Codeină Slavia

Do not use Codeină Slavia 15 mg after the expiry date stated on the package after EXP. The expiry date refers to the last day of that month.

Store at temperatures below 25°C, in the original package.

Keep out of the sight and reach of children.

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 protect the environment.

6. Package contents and other information

What does Codeină Slavia contain

- The active ingredient is codeine phosphate hemihydrate 15 mg.
 - Other ingredients: lactose monohydrate, maize starch, talc, magnesium stearate, povidone K 30.
- Each tablet contains 80 mg lactose monohydrate.

What Codeină Slavia looks like and package composition

Codeine Slavia 15 mg is presented as white, flat tablets with a diameter of 7 mm.

Box containing 2 Al/PVC blisters, each with 10 tablets.

Marketing authorization holder and manufacturer

Marketing authorization holder

S.C. Slavia Pharm S.R.L.

44C Theodor Pallady Blvd.

032266, Bucharest, Romania

This leaflet was revised in September 2024.