

Bijsluiter: informatie voor de patiënt

Codeïnefosfaat Schmid Pharma 10 mg, tabletten
Codeïnefosfaat Schmid Pharma 15 mg, tabletten
Codeïnefosfaat Schmid Pharma 20 mg, tabletten
Codeïnefosfaat Schmid Pharma 30 mg, tabletten

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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 or pharmacist.
- This medicine has been prescribed for you (or for your child) 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [nationally completed name] is and what it is used for
2. What you need to know before you take [nationally completed name]
3. How to take [nationally completed name]
4. Possible side effects
5. How to store [nationally completed name]
6. Contents of the pack and other information

1. What [nationally completed name] is and what it is used for

[Nationally completed name] contains the active substance codeine. It belongs to the group of weak pain medications, so called opioid analgesics, and can be used alone or in combination with other pain medication such as paracetamol. Codeine is also used to treat coughing (by suppressing the cough) and diarrhoea (by its action on the gut).

[Nationally completed name] is used for:

- short-term relief of moderate pain that cannot be relieved by other pain medication like (only) paracetamol or ibuprofen in adults and children older than 12 years of age,
- treatment of symptoms of a dry cough in adults and children older than 12 years of age,
- treatment of symptoms of diarrhoea in adults if treatment with loperamide (a diarrhoea

medicine) did not work well.

2. What you need to know before you take [nationally completed name]

Do not take [nationally completed name]

- if you are allergic to codeine or any of the other ingredients of this medicine (listed in section 6).
- if you have problems breathing or other prolonged lung diseases.
- if you are being treated for asthma.
- if you have liver problems.
- if you drink too much alcohol (alcoholism).
- if you have an increased risk of constipation.
- if you have serious stomach cramps with bouts of pain caused by gall stones.
- if you have severe diarrhoea.
- if you have had a head injury (for example due to an accident) or if you have had an increased pressure in the brain (may cause painful eyes, changes in sharp vision or a headache behind the eyes).
- if you are younger than 12 years of age.
- to treat pain after surgical removal of tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome. This applies to children and adolescents up to 18 years of age because of the risk of a serious and life-threatening side effect.
- if you are breast-feeding.
- if you know that your body very quickly converts codeine into morphine
- if you use mono-amine-oxidase (MAO) inhibitors (a certain group of medicines to treat serious depression), or if you have used a medicine from this group in the past 14 days.

Warnings and precautions

Talk to your doctor before taking [nationally completed name] if the following applies to you:

- you have had epileptic attacks or convulsions (uncontrollable body shocks, often as part of an epileptic seizure)
- you have a serious mental illness in which the control of your behaviour and actions is disturbed (toxic psychosis)
- you have a shock
-
- you have heart problems, in particular an abnormally fast heart rhythm (supraventricular tachycardia)
- you have asthma or problems breathing
- you have an intestinal disease with inflammation of the intestines, including bloody

- diarrhoea (pseudomembranous colitis);
- you have recently had an operation of the digestive tract or the urinary tract
 - you have suddenly occurring abdominal problems
 - you have a liver or kidney disorder
 - you have a gall bladder disorder or gall stones
 - you have difficulty urinating due to an enlarged prostate or because of another reason
 - you have high blood pressure caused by a tumour in the kidneys (pheochromocytoma)
 - your adrenal glands do not function well (Addison's disease)
 - you have a certain form of muscle weakness (myasthenia gravis)
 - you have low blood pressure or a slow acting thyroid
 - you have had trouble with alcoholism, drug abuse or drug addiction
 - you are pregnant
 - you are elderly or in poor health

Use of [nationally completed name] can cause constipation. It may therefore be necessary to take a medicine to improve defecation (laxative) in addition (only if you do not use [nationally completed name] to treat diarrhoea).

Do not use [nationally completed name] any longer than has been prescribed by your doctor. Regular use of [nationally completed name] for a prolonged period of time may cause dependency, meaning that you are not able to live without this medicine. If you are dependent and suddenly stop taking the tablets, you may experience restlessness and irritability. Taking a pain medicine for headache on a long term regular basis or taking too much of it may actually worsen the headache.

A liver enzyme converts codeine in your body into morphine. Morphine is the substance that produces the effects of codeine and relieves pain and symptoms of cough. Some people have a variation of this enzyme which may have an effect in various ways. In some people, morphine is not produced or is only produced in very small amounts, [nationally completed name] will cause insufficient relief of the pain or cough. In other people, a very large amount of morphine is produced, so there is a higher risk of getting serious side effects. If you notice one of the following side effects, you must stop using [nationally completed name] and immediately seek medical advice: slow and superficial breathing, confusion, drowsiness, small pupils, nausea or vomiting, constipation, lack of appetite.

Children and adolescents up to 18 years of age

Use in children and adolescents up to 18 years of age after an operation

[Nationally completed name] must not be used as pain medicine in children and adolescents up to 18 years of age after surgical removal of their tonsils or adenoids because of the risk to develop

obstructive sleep apnoea syndrome, which is a serious and life-threatening side effect (see above “Do not take [nationally completed name]”).

Use in children with respiratory problems

[Nationally completed name] is not recommended for children with respiratory problems, because symptoms of morphine toxicity could possibly be worse.

Adolescents older than 12 years of age;

[Nationally completed name] is not recommended for the treatment of cough in adolescents with a reduced respiratory function.

[Nationally completed name] is not recommended for the treatment of diarrhoea in children and adolescents under the age of 18 years.

Other medicines and [nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription

Tell your doctor or pharmacist, especially if you use one of the following medicines for the treatment of:

- depression or Parkinson's disease (mono-amine-oxidase (MAO) inhibitors, such as moclobemide, linezolid or selegiline). [Nationally completed name] must not be used together with MAO inhibitors and may only be taken two weeks after you have stopped taking the MAO inhibitors (see above “Do not take [nationally completed name]”).
- depression (tricyclic antidepressants), such as amitriptyline
- nausea and vomiting: metoclopramide or domperidone
- irregular heart beat: mexiletine or quinidine
- diarrhoea: loperamide or kaolin
- ulcers: cimetidine
- high blood pressure
- AIDS, such as Ritonavir
- allergies: so called antihistamines, they may cause drowsiness
- slow heart rate: atropine
- sleeplessness
- irritability, excitement or anxiety (sedatives or calming medicines)
- severe pain (stronger pain medicines compared to [nationally completed name])
- pain during operations (anaesthetics)
- toxicity or drug dependency: buprenorphine, naltrexone, naloxone
- narcolepsy: sodium oxybate

Simultaneous use of [nationally completed name] and calming medicines (such as benzodiazepines or medicines that are similar) increases the risk of drowsiness, difficulty breathing (respiratory depression) and unconsciousness (coma) and may be life-threatening. Simultaneous use of these medicines may only be considered if no other treatments are possible.

If your doctor prescribes [nationally completed name] together with such calming medicines, the dose must be as low as possible and duration of treatment should be as brief as possible.

Inform your doctor about all calming products you use and strictly follow the dose advice. It may be useful to inform friends and family about the above-mentioned symptoms. Contact your doctor at once if you experience one of these symptoms.

[Nationally completed name] with alcohol

Do not drink alcohol when using this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

[Nationally completed name] should only be used during pregnancy if strictly necessary. Regular use during pregnancy can cause withdrawal symptoms (physical and mental problems) in the newborn baby after treatment discontinuation.

Do not take [nationally completed name] if you are breast-feeding. Codeine and morphine are excreted in the breast milk.

Driving and using machines

[Nationally completed name] may cause, among others, confusion, somnolence, dizziness, hallucinations, blurred or double vision or convulsions. Therefore, this medicine can affect the ability to drive or use machines. Talk to your doctor or pharmacist if you are not sure whether it is safe to drive if you are taking [nationally completed name]. Do not use machines if you feel you are less attentive than normal.

[Nationally completed name] contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take [nationally completed name]

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

The recommended dose is:

Adults and children over 12 years of age

For mild to moderate pain:

30 to 60 mg 4 times per day (every 6 hours) based on the need. Do not take more than 240 mg in 24 hours.

For coughing:

15 to 30 mg 3 to 4 times per day.

This medicine is not recommended to treat coughing in adolescents over 12 years of age with respiratory problems.

For diarrhoea:

[Nationally completed name] is not recommended for the treatment of diarrhoea in children and adolescents under the age of 18 years.

Adults: 15 to 60 mg 3 to 4 times per day.

Patients with liver or kidney disorders

Your doctor may prescribe a lower dose if you have a liver or kidney disorder. Do not take more than the prescribed amount and strictly follow your doctor's advice.

Method of administration

[Nationally completed name] is for oral use. Swallow your tablets with a glass of water.

Duration of treatment

Pain treatment with [nationally completed name] must be limited to 3 days. Please consult your doctor if your pain does not decrease after 3 days.

If you take more [nationally completed name] than you should

If you realise you have taken more [nationally completed name] than your doctor has recommended (or if someone else has taken some of your [nationally completed name]), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

Symptoms of an overdose are, among others, a sick feeling, confusion, convulsions, dizziness, nervousness, restlessness, excitement, hallucinations, muscle weakness, drowsiness, fatigue, low blood pressure, constricted pupils, slow respiration and fast heartbeat.

If you forget to take [nationally completed name]

If you miss a dose and if it is almost time for the next dose, skip the missed dose and continue your normal dose regime. Do not take a double dose to make up for a forgotten dose.

If you stop taking [nationally completed name]

Do not stop taking your tablets without talking to your doctor first. You must continue treatment as

long as your doctor considers it necessary.

If you suddenly stop, the following withdrawal symptoms may occur: shaking, sleeplessness, restlessness, irritability, anxiety, depression, lack of appetite, nausea, vomiting, diarrhoea, sweating, tearing, runny nose and sneezing, yawning, getting goose bumps, pupil dilation, weakness, fever, muscle cramp, dehydration, fast heartbeat, increased respiration and elevated blood pressure.

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

4. Possible side effects

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

Rare side effects (may affect up to 1 in 1,000 people)

- Severe allergic reaction (called anaphylaxis) which may cause swelling of the face, tongue and throat, difficulty in breathing or shock. Stop taking [nationally completed name] immediately and contact your doctor at once if you experience such symptoms.
- Gastrointestinal problems leading to constipation
- Inflammatory bowel disease (may become chronic), which causes abdominal pain and diarrhea mixed with blood

Other side effects (frequency cannot be estimated from the available data)

- Allergic reactions like skin rash, urticaria, pruritus, shortness of breath, unusual sweating, red skin or excessive blushing, swollen feet and ankles
- Mood changes, depression, hallucination, restlessness, agitation, nightmares, confusion, disorientation, tolerance or dependency of [nationally completed name], reduced sexual desire
- Somnolence, general feeling of being ill or without energy, fatigue, dizziness, seizure, headache, very low body temperature, increased pressure in the head which may cause painful eyes, difficulties to see sharp or headache behind the eyes
- Narrowing of the eye pupils, blurred vision or double vision
- Slower than normal heart rate, rapid heartbeat, feeling like your heart is pounding, racing or has skipped beats
- Fainting, low blood pressure, low blood pressure when standing up which may make you feel dizzy and lead to falls
- Suppressed breathing, especially when taking higher doses of [nationally completed name]
- Constipation (also with long-term use of [nationally completed name]), abdominal pain, inflammation of the pancreas, nausea, vomiting, dry mouth
- Dull, steady or intermittent pain in the upper abdomen (biliary colic)
- Muscle stiffness

- Pain during urinating, urinating less often a lower amount of urine, difficulty in passing urine
- Inability to get or keep an erection
- Reduced appetite
- Weakness, fatigue
- Withdrawal symptoms, see above under “If you stop taking [nationally completed name]”

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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, blister and container after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

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 [nationally completed name] contains

- The active substance is codeine phosphate hemihydrate.

{[Nationally completed name] 10 mg tablets}

Each tablet contains 10 mg codeine phosphate hemihydrate equivalent to 7.37 mg of codeine.

{[Nationally completed name] 15 mg tablets}

Each tablet contains 15 mg codeine phosphate hemihydrate equivalent to 11.05 mg of codeine.

{[Nationally completed name] 20 mg tablets}

Each tablet contains 20 mg codeine phosphate hemihydrate equivalent to 14.73 mg of codeine.

{[Nationally completed name] 30 mg tablets}

Each tablet contains 30 mg codeine phosphate hemihydrate equivalent to 22.10 mg of codeine.

- The other ingredients are:

Microcrystalline cellulose, lactose monohydrate, potato starch, colloidal anhydrous silica, talc, magnesium stearate.

What [Nationally completed name] looks like and contents of the pack

{[Nationally completed name] 10 mg tablets}

White or almost white, biconvex tablet of round shape (diameter 6 mm), debossed 'COD' over '10' on one side.

{[Nationally completed name] 15 mg tablets}

White or almost white, biconvex tablet of round shape (diameter 7 mm), debossed 'COD' over '15' on one side.

{[Nationally completed name] 20 mg tablets}

White or almost white, biconvex tablet of round shape (diameter 8 mm), debossed 'COD' over '20' on one side.

{[Nationally completed name] 30 mg tablets}

White or almost white, biconvex tablet of round shape (diameter 9 mm), debossed 'COD' over '30' on one side.

PVC//Alu blister:
30 tablets

HDPE container:
250 tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder

Schmid Pharma BV
Blokweg 8
4671 RA Zevenbergen
The Netherlands

Fabrikant

Meditop Pharmaceutical Ltd.

Ady Endre street 1
2097 Pilisborosjenő
Hongarije

In het register ingeschreven onder:

Codeïnefosfaat Schmid Pharma 10 mg, tabletten - RVG 127427
Codeïnefosfaat Schmid Pharma 15 mg, tabletten - RVG 127428
Codeïnefosfaat Schmid Pharma 20 mg, tabletten - RVG 127429
Codeïnefosfaat Schmid Pharma 30 mg, tabletten - RVG 127430

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Tsjechië: Kodein Schmid Pharma 10, 15, 20, 30 mg tablety
Nederland: Codeïnefosfaat Schmid Pharma 10, 15, 20, 30 mg, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in april 2025