

## Package leaflet: information for the patient

Codeine phosphate Costero 10 mg, tablets  
Codeine phosphate Costero 15 mg, tablets  
Codeine phosphate Costero 20 mg, tablets  
Codeine phosphate Costero 30 mg, tablets  
codeine phosphate hemihydrate

Read the entire 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.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you or your child. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

## Contents of this leaflet

1. What is Codeine Phosphate Costero and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
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### 1. What is Codeine Phosphate Costero and what is this medicine used for?

This medicine contains codeine. Codeine belongs to a group of weak painkillers. It can be used on its own or together with other painkillers, such as paracetamol. This medicine is also used for the treatment of symptoms associated with coughing (by suppressing the cough). It can also be used for the treatment of symptoms associated with diarrhea (by acting on the intestines).

### This medicine is used for:

a short treatment of moderate pain that is not relieved by other painkillers, such as paracetamol alone or ibuprofen alone, in adults and children aged 12 years and older.  
the treatment of symptoms associated with dry cough, in adults and children aged 12 years and older.  
the treatment of symptoms associated with diarrhea. This applies to adults for whom treatment with loperamide (an antidiarrheal) has not worked well.

### 2. When should you not use this medicine or be extra careful with it?

#### When should you not use this medicine?

if you are allergic to codeine phosphate or any of the other ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.  
if you have breathing problems or if you have other long-term lung diseases.  
if you are being treated for asthma.  
if you have liver problems.  
if you drink too much alcohol (alcoholism).  
if you have a higher risk of intestinal obstruction.

if you suffer from severe stomach cramps with bouts of pain. This is caused by gallstones.

if you have severe diarrhea.

if you have had a head injury (for example, due to an accident). Or if you have experienced high pressure in the brain (can cause painful eyes, blurred vision, or headache behind the eyes).

if you are under 12 years old.

to reduce pain after surgery where the tonsils or adenoids have been removed. This applies to children and adolescents up to 18 years old, due to the risk of obstructive sleep apnea syndrome. This is a serious and fatal side effect, where the tongue and soft parts of the throat can stop breathing.

if you are breastfeeding gives.

if you know that you metabolize this medicine into morphine very quickly.

if you are using monoamine oxidase (MAO) inhibitors (a group of medicines for severe depression). Or if you have used a medicine from this group in the last 14 days.

When should you be extra careful with this medicine?

Contact your doctor before using this medicine if the following applies to you:

if you have had epileptic seizures or convulsions (cramping of your muscles and jerking throughout your body. This is often part of an epileptic seizure)

if you suffer from a severe mental illness, where you have a problem with controlling your own behavior and actions (toxic psychosis)

if you are in shock

if you have a heart problem, especially if your heart beats faster than normal (supraventricular tachycardia)

if you suffer from asthma or if you have breathing problems

if you have an intestinal disease with inflammation of the intestines, such as bloody diarrhea (pseudomembranous colitis)

if you have recently had surgery on the gastrointestinal tract or urinary tract

if you suffer from sudden abdominal complaints

if you have kidney disease or liver disease

if you have gallstones or a disease of the gallbladder

if you have difficulty urinating due to a prostate that is larger than normal, or for another reason

if have high blood pressure due to a swelling in the adrenal glands (pheochromocytoma)

if your adrenal glands do not function properly (Addison's disease)

if you have a muscle disease. Your muscles are very weak (myasthenia gravis)

if you have low blood pressure or if your thyroid works too slowly

if you have had problems with excessive alcohol consumption (alcoholism), drug abuse, or drug addiction

if you are pregnant am

if you are elderly or in poor health

The use of this medication can cause constipation. It may therefore be necessary to use it together with Codeine Phosphate Costero to take a medicine to improve bowel movements (laxative). This is only possible if you are not using Codeine Phosphate Costero for the treatment of diarrhea.

Do not use this medicine longer than advised by your doctor, pharmacist, or nurse. Are you using this medicine regularly and for a long time? Then you may not be able to do without this medicine (you are dependent). If you are dependent and suddenly stop taking the tablets, you may become restless and irritable. If a painkiller for headaches is taken regularly and for too long or too much, the headache may actually get worse.

Codeine is converted into morphine by an enzyme in the liver. Morphine is responsible for the effect of this medicine. It reduces pain and cough symptoms. Some people have a different type of this enzyme. Therefore, this medicine can work in different ways in people. In some people, codeine is not converted into morphine, or only a very small amount. As a result, this medicine does not work well enough to reduce pain or cough symptoms. Other people have a higher risk of severe side effects because a lot of morphine is produced. If you experience any of the following side effects, you should stop using this medicine and seek medical advice immediately: slow or shallow breathing, confusion, drowsiness, small pupils, nausea or vomiting, constipation, loss of appetite.

#### Children and adolescents up to 18 years

Use in children and adolescents up to 18 years after surgery

This medicine should not be used to relieve pain after surgery to remove tonsils (tonsillectomy) or adenoids (adenoidectomy). This applies to children and adolescents up to 18 years, due to the risk of obstructive sleep apnea syndrome. This is a serious and potentially fatal side effect, where the tongue and soft parts of the throat can block breathing (see section "When should you not use this medicine?").

#### Use in children with breathing problems

This medicine is not recommended for children who have breathing problems. The symptoms of morphine toxicity can be more severe in these children.

#### Adolescents over 12 years

This medicine is not recommended for adolescents who have difficulty breathing for the treatment of cough.

This medicine is not recommended for the treatment of diarrhea in children and adolescents under 18 years.

#### Are you using any other medicines?

In addition to Codeine Phosphate Costero are you using any other medicines, have you recently done so, or are you planning to do so soon? Then tell your doctor or pharmacist. Do this especially if you are using any of the following medicines for the treatment of:

depression or Parkinson's disease (monoamine oxidase (MAO) inhibitors, such as moclobemide, linezolid or selegiline). Codeine phosphate Costero must not be used together with MAO inhibitors. Codeine phosphate Costero can only be used two weeks after stopping the use of MAO inhibitors (see section 'When should you not use this medicine').

depressions (tricyclic antidepressants, such as amitriptyline)  
nauseous nausea and vomiting (metoclopramide or domperidone)  
irregular heartbeat (mexiletine or quinidine)  
diarrhea (loperamide or kaolin)  
stomach ulcers (cimetidine)

high blood pressure  
the AIDS virus (such as ritonavir)  
allergies (antihistamines; this may cause drowsiness)  
a slow heart rhythm (atropine)  
sleeping pills (medicines to help sleep)  
irritation, excitement or anxiety (medicines that calm you (sedatives) or tranquilizers)  
severe pain (stronger painkillers than Codeine Phosphate Costero)  
pain during surgeries (medicines to anesthetize (anesthetics))  
poisoning from drugs or dependence on them (buprenorphine, naltrexone, naloxone)  
suddenly falling asleep (narcolepsy) (sodium oxybate)

The use of Codeine Phosphate Costero together with sedatives (such as benzodiazepines or other medications that reduce anxiety and tension) increases the risk of drowsiness, difficulty breathing (respiratory depression), and unconsciousness (coma). This can be fatal. The use of Codeine Phosphate Costero together with sedatives should only be considered if no other treatments are possible. Does your doctor advise this medication together with sedatives? Then the dose should be as low as possible and the medications should be used for as short a time as possible.

Inform your doctor about all sedatives you are using. Follow your doctor's advice on the dosage carefully. It may help to tell friends and family about the symptoms mentioned above. Contact your doctor if you experience these symptoms.

What should you watch out for with alcohol?  
Do not drink alcohol while using this medication.

Pregnancy, breastfeeding, and fertility  
Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medication.

Use this medication only if you are pregnant if it is really necessary. Do you use this medication regularly while pregnant? Then this can cause the newborn baby to experience withdrawal symptoms (physical and mental symptoms) after stopping this medication.

Do not use this medication if you are breastfeeding. Codeine and morphine pass into breast milk.

Driving ability and the use of machines  
This medication can cause you to become confused, drowsy, dizzy, see, feel, or hear things that are not there (hallucinations), have blurred or double vision or experience convulsions (muscle cramps and jerking throughout your body. This is often part of an epileptic seizure). Therefore, this medication can affect how well you can drive or use machines. Are you unsure if it is safe to drive while using this medication? Then contact your doctor or pharmacist. Do not use machines if you are less attentive than usual.

Codeine Phosphate Costero contains lactose  
If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

### 3. How to use this medicine?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

The recommended dosage is:  
Adults and children over 12 years

For mild to moderate pain:  
30 to 60 milligrams (mg) up to 4 times a day (every 6 hours) as needed. Do not take more than 240 mg in 24 hours.

For cough:  
15 to 30 mg, 3 to 4 times a day.  
This medicine is not recommended for adolescents over 12 years with breathing problems for the treatment of cough.

For diarrhea:  
This medicine is not recommended for the treatment of diarrhea in children and adolescents up to 18 years. Adults: 15 to 60 mg, 3 to 4 times a day.

Patients with liver disease or kidney disease  
Your doctor may advise a lower dose if you have liver disease or kidney disease. In that case, it is very important to follow your doctor's advice.

Method of use  
This medicine is for oral use. Swallow the tablets with a glass of water.

Duration of treatment  
This medicine should not be used for more than 3 days. Is the pain not reduced after 3 days? Then contact your doctor.

Have you taken too much of this medicine?  
Have you taken more of this medicine than your doctor advised (or has someone else taken your medicine)? Then contact your doctor immediately. If you cannot reach your doctor, go to the nearest hospital and take the packaging with you.

Symptoms of an overdose include: feeling sick, being confused, muscle spasms and convulsions throughout your body, dizziness, nervousness, restlessness, excitement, seeing, feeling, or hearing things that are not there (hallucinations), muscle weakness, drowsiness, fatigue, low blood pressure, pupils smaller than normal, slow breathing, and rapid heartbeat.

Did you forget to take this medicine?  
Have you missed a dose and is it almost time for the next dose? Then skip the missed dose and continue with your regular dosing schedule.

If you stop taking this medicine  
Do not stop taking the tablets without talking to your doctor. You should continue the treatment if your doctor deems it necessary.

If you stop suddenly, the following withdrawal symptoms may occur: tremors, sleep problems, restlessness, irritability, anxiety, depression, decreased appetite, nausea, vomiting, diarrhea, sweating, tearing, runny nose and sneezing, yawning, goosebumps, dilation of the pupil, weakness, fever, muscle cramps, dehydration, faster heartbeat than normal, faster breathing than normal, or high blood pressure.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

#### 4. Possible side effects

Like any medicine, this medicine can also have side effects. Not everyone experiences them.

Rare (occur in less than 1 in 1,000 users)

Severe allergic reaction (anaphylaxis). This can cause swelling of the face, tongue, and throat, breathing difficulties, or shock. Are you experiencing this? Stop taking this medicine immediately and contact your doctor.

Stomach and intestinal problems that can cause constipation

Intestinal disease with inflammation (may not resolve). This can cause abdominal pain and diarrhea with blood in it

Not known (cannot be determined from the available data)

Allergic reactions such as skin rash, rash with pink bumps and severe itching (urticaria), itching, difficulty breathing, more sweating than usual, red skin or excessive flushing, swollen ankles and feet

Changes in your emotions, depression, seeing, feeling, or hearing things that are not there (hallucinations), being restless, nervous, excited or agitated, nightmares, being confused, being so confused that you can no longer recognize people, places, or things (disorientation), becoming accustomed to this medication (it works less effectively) or feeling unable to do without this medication, decreased libido

Feeling drowsy, feeling sick or unwell, being tired, feeling dizzy, seizures (muscle spasms and jerking throughout your body, often as part of an epileptic seizure), headache, very low body temperature, high pressure in the head (can cause painful eyes, blurred vision, or headache behind the eyes)

Small pupils, blurred vision or double vision

Your heart beats slower than normal, your heart beats faster than normal, palpitations, rapid or irregular heartbeat

Fainting, low blood pressure, low blood pressure upon standing, which can make you feel dizzy and cause you to fall

Breathing less frequently, especially when taking a high dose of this medication

Constipation (can occur if you use this medication for a long time), abdominal pain, inflammation of the pancreas, feeling nauseous, vomiting, dry mouth

Dull pain, persistent pain or painful cramps in the upper abdomen (biliary colic) • Stiff muscles

Pain when urinating, urinating less frequently, urinating less volume, difficulty urinating

Difficulty getting or maintaining an erection

Decreased appetite

A weak feeling, tired are

Complaints due to stopping this medicine (withdrawal symptoms), see section "If you stop taking this medicine"

## Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you help us obtain more information about the safety of this medicine.

## 5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find this on the box and the blister pack after "EXP:". It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

## 6. Contents of the pack and other information

What substances are in this medicine?

- The active substance in this medicine is codeine phosphate hemihydrate

Codeine phosphate Costero 10 mg, tablets

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

Codeine phosphate Costero 15 mg, tablets

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

Codeine phosphate Costero 20 mg, tablets

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

Codeine phosphate Costero 30 mg, tablets

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

- The other ingredients in this medicine are:

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

What does Codeine Phosphate Costero look like and what is in a package?

Codeine Phosphate Costero 10 mg, tablets

White or almost white, round, biconvex tablets (diameter 6 mm), with inscription 'COD' over '10' on one side.

Codeine Phosphate Costero 15 mg, tablets

White or almost white, round, biconvex tablets (diameter 7 mm), with inscription 'COD' over '15' on one side.

Codeine Phosphate Costero 20 mg, tablets

White or almost white, round, biconvex tablets (diameter 8 mm), with inscription 'COD' over '20' on one side.

Codeine phosphate Costero 30 mg, tablets

White or almost white, round, biconvex tablets (diameter 9 mm), with inscription 'COD' over '30' on one side.

Codeine phosphate Costero 10 mg, 20 mg, tablets

PVC/Alu blister: 30 tablets

HDPE container closed with a tamper-evident PP cap: 250 tablets

Codeine phosphate Costero 15 mg, 30 mg, tablets

PVC/Alu blister: 10, 30 tablets

It is possible that not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Costero B.V.

Olympic Stadium 24

1076DE Amsterdam

The Netherlands

Manufacturer

Meditop Pharmaceutical Ltd.

Ady Endre street 1

2097 Pilisborosjenő

Hungary

This medicine is registered under:

Codeine phosphate Costero 10 mg, tablets - RVG 127423

Codeine phosphate Costero 15 mg, tablets - RVG 127424

Codeine phosphate Costero 20 mg, tablets - RVG 127425

Codeine phosphate Costero 30 mg, tablets - RVG 127426

This medicine is registered in member states of the European Economic Area under the following names:

Czech Republic: Kodein Schmid 10, 15, 20, 30 mg tablets

Netherlands: Codeine phosphate Costero 10, 15, 20, 30 mg, tablets

This leaflet was last approved in April 2025