

**PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Cod Acamol® 15/325 Tablets

Composition

Each tablet contains:

Paracetamol 325 mg

Codeine Phosphate 15 mg

For information on the safety and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of the medicine" and section 6 – "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is not intended for children below 12 years of age.

- **Prolonged use may cause dependence!**
- **This medicine contains codeine which is an opioid that can cause addiction. You can develop withdrawal symptoms if you stop use abruptly.** Consult the doctor if needed.

Medicines containing codeine should only be used for treatment of acute pain (of short duration) of moderate intensity in adolescents above 12 years of age and only if the pain cannot be treated by pain relievers such as paracetamol or ibuprofen; this is in view of the fact that use of codeine may increase the risk of respiratory depression.

Medicines from the opioid group may cause addiction, especially with prolonged use, and have the potential for misuse and overdose. A reaction to an overdose can be manifested by slow breathing and can even cause death. Make sure you know the name of the medicine, the dosage you are taking, the frequency of administration, the duration of treatment, the side effects and the potential risks.

Additional information about the risk of dependence and addiction can be found at the link:

https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for relief of pain of moderate intensity, for reduction of fever and relief of cough associated with fever.

Therapeutic group:

Paracetamol: pain reliever and fever reducer.

Codeine phosphate: a pain reliever from the opioid group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine (see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information")
- You suffer from severe kidney or liver disease
- You know that you produce a large quantity of morphine from codeine (ultra-rapid metabolizers)
- You are breastfeeding
- You suffer from asthma or other breathing problems, for example, chronic bronchitis or emphysema
- You have just had a head injury or suffer from increased pressure on the brain
- You drink a lot of alcohol, or have done so in the past
- You have recently had a gallbladder operation
- You have diarrhea
- You are taking monoamine oxidase inhibitors (MAOIs) or took them within the last two weeks. MAOIs such as phenelzine, moclobemide or isocarboxazid are medicines used to treat depression
- **The patient is a child below 12 years of age**
- You are an adolescent below 18 years of age after surgery for removal of tonsils or adenoids due to obstructive sleep apnea syndrome (sleep disruption due to respiratory pauses), since these patients are more prone than others to suffer from breathing problems.

Special warnings regarding use of the medicine

If you developed skin side effects in the past as a result of taking preparations containing paracetamol, do not take preparations containing paracetamol, so that severe skin effects will not recur.

Paracetamol may cause liver damage in the following cases: when given at a dosage higher than that recommended, when given for a prolonged period, when drinking excessive alcoholic beverages during the treatment period or if you have done so in the past, and when taking additional medicines that affect liver activity.

The medicine is not recommended for treatment of cough and common cold in adolescents aged 12-18 years suffering from a breathing problem.

Avoid taking a high dosage of this medicine (even if within the recommended dosage range) while fasting.

To prevent paracetamol overdose or poisoning – do not take additional medicines to reduce fever and relieve pain or cold medicines containing paracetamol without consulting a doctor or pharmacist.

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

Taking codeine regularly for a prolonged period of time may cause addiction that may cause you to feel restless and nervous when you stop taking the medicine.

Taking a pain reliever for headaches too often or for too long a period of time may cause the headaches to get worse.

Before treatment with Cod Acamol, tell the doctor if:

- You are elderly or weak
- You have stomach pains or other sudden abdominal problems
- You have an underactive thyroid gland
- You have liver or kidney problems, because the dosage might need to be lowered
- You have severe muscle weakness (myasthenia gravis, muscle weakness, weakness of facial muscles, including the eye muscles, and difficulty in swallowing)
- You have a disease of the biliary tract
- You have problems with your adrenal glands (Addison's disease)
- You suffer from an enlarged prostate gland (in males) or narrowing of the urethra (tube through which urine passes).

Before treatment with this medicine, tell the doctor who prescribed it for you if you:

- Are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs
- Have previously suffered from withdrawal symptoms, such as restlessness, agitation, anxiety, shaking or sweating, when you stopped taking alcohol or medicines
- Feel you need to take more of Cod Acamol tablets to get the same level of pain relief; you may be developing tolerance to the effects of the medicine or dependence on the medicine. Consult the doctor, who will determine whether the dosage of the medicine needs to be changed or if an alternative pain reliever should be prescribed for you.

Taking this medicine regularly, particularly for a long time, can cause addiction. The doctor will explain to you how long you should be taking the medicine and when it can be discontinued, how to do this safely. Rarely, increasing the dosage of the medicine can make you more sensitive to pain. If this happens, speak to the doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking the medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, nervousness, agitation, anxiety, feeling your heartbeat (palpitations), high blood pressure, nausea or vomiting, diarrhea, loss of appetite, tremor or sweating. Your doctor will discuss with you how to gradually reduce the dosage before stopping the medicine. It is important that you do not stop taking the medicine suddenly, as it may increase the chance of onset of withdrawal symptoms.

Opioids are only indicated for the people for whom they were prescribed. Do not give your medicine to anyone else. Taking higher or more frequent dosages may increase the risk of addiction. Overuse or misuse can lead to overdose and/or death.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that brings pain relief. Some people have a variation of this enzyme, which can affect such people in different ways. In some people, morphine is not produced or is produced in very small quantities, and the pain relief will therefore be inadequate. Other people are more likely to get serious side effects because they produce a very high amount of morphine. This tendency is more common in populations of African Ethiopian origin (frequency of 29% in this population). If you notice any of the following side effects, stop taking this medicine and seek immediate medical care: slow or shallow breathing, confusion, sleepiness, small pupils, nausea or vomiting, constipation, lack of appetite.

Use in children and adolescents

The medicine is not intended for use in children under 12 years of age.

Use in adolescents after surgery – Codeine should not be used for pain relief in adolescents after removal of their tonsils or adenoids due to obstructive sleep apnea syndrome (a sleep disturbance due to respiratory pauses), since they may be at increased risk of severe side effects in case of morphine toxicity.

For adolescents over 12 years of age, medicines that contain codeine should only be used to treat acute pain (of short duration) of moderate intensity, and only if the pain cannot be treated with other pain relievers such as paracetamol or ibuprofen. This is due to the fact that codeine may increase risk of respiratory depression.

Drug interactions

If you are taking, or have recently taken, or if you may take, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- A monoamine oxidase inhibitor (MAOI) used to treat depression (do not use the medicine if")
- Sedatives and hypnotics, e.g., temazepam and diazepam
- Phenothiazines (sedatives) or tricyclic antidepressants
- Antihypertensives, diuretics
- Medicines for irregular heartbeats (mexiletine, quinine or quinidine)
- Medicines used to dry fluids in the mouth and lungs, known as anticholinergics
- Medicines to treat diarrhea or nausea (metoclopramide, domperidone)
- Medicines used to treat problems of the stomach, gallbladder, heartburn or nausea (e.g., cimetidine, colestyramine)
- Sodium oxybate used to treat sleepiness and sudden loss of muscle tone
- Other strong painkillers called opioids
- Medicines which prevent blood clotting (anticoagulants such as warfarin)
- Do not take other medicines containing paracetamol or codeine whilst taking Cod Acamol. Some medicines which can be bought without a prescription may contain paracetamol or codeine; therefore, always check the ingredients listed on the package.

Cod Acamol may interfere with some laboratory tests used for determining some diseases.

Concomitant use of Cod Acamol and sedative medicines such as benzodiazepines or similar medicines, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use of Cod Acamol and sedatives should only be considered when other treatment options are not possible.

However, if your doctor still prescribes for you Cod Acamol together with sedative medicines – the dosage and duration of concomitant treatment of Cod Acamol with the sedatives should be limited by the doctor.

Tell your doctor about all sedative medicines you are taking and follow your doctor's dosage recommendations closely. It is recommended that you inform friends and relatives to be aware of the signs and symptoms stated above. Refer to your doctor when you experience such symptoms.

Use of the medicine and food

Swallow the tablets with a glass of water.

Use of the medicine and alcohol consumption

Do not consume alcohol during the course of treatment with Cod Acamol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult the doctor or pharmacist before commencing treatment with the medicine.

Pregnancy:

Do not take Cod Acamol if you are pregnant or think you might be pregnant unless you have consulted your doctor and the benefits of treatment may outweigh the potential harm to the baby.

If you use Cod Acamol during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breastfeeding:

Do not take Cod Acamol while you are breastfeeding as codeine passes into breast milk and will affect your baby.

Driving and operating machinery

Cod Acamol may cause dizziness or drowsiness. Do not drive or operate machinery if you are affected in this way by taking the medicine. Codeine may cause vision disturbances.

The medicine may affect your ability to drive as it may make you sleepy or dizzy.

Do not drive while taking this medicine until you know how it affects you.

Talk to the doctor or pharmacist if you are unsure if it is safe for you to drive while taking this medicine.

Adolescents (over the age of 12 years) should be cautioned against riding a bicycle or playing near the road and the like.

Important information about some of the ingredients of the medicine

The medicine contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to certain sugars, refer to your doctor before taking this medicine.

This medicine contains less than 23 mg sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine. The doctor should discuss with you the duration of treatment with the medicine. The doctor will arrange a plan for stopping treatment that will include an explanation of how to gradually reduce the dosage until full discontinuation of its use. The dosage and treatment regimen will be determined by the doctor only.

The usual dosage unless otherwise instructed by the doctor:

Adults and adolescents above 12 years of age:

1-2 tablets every 4-6 hours, as needed. Do not exceed a dosage of 8 tablets in 24 hours.

The medicine is not intended for use in children under 12 years of age, due to risk of serious breathing problems.

Do not exceed the recommended dose.

If you feel the effect of Cod Acamol is too strong or too weak or your symptoms persist, refer to the doctor or pharmacist.

This medicine should not be taken for more than three days. If the fever persists for more than 3 days or if there is no pain relief within 3 days, discontinue use and refer to the doctor.

If you are elderly or if you have other medical problems, you may need a lower dosage. Check with your doctor about this.

Instructions for use

Do not chew. There is no information regarding crushing.

The tablets can be halved on the score line. Swallow the tablets with a glass of water.

If you took an overdose or if a child has accidentally swallowed the medicine,

immediately refer to a doctor or proceed to a hospital emergency room and bring the medicine package with you. Even if you feel well, immediate care is critical, **due to risk of development of severe liver damage.**

If you forgot to take this medicine

at the required time, take the next dose at the usual time. Do not take two doses together to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Do not suddenly stop taking this medicine. Before discontinuing use of the medicine, first consult your doctor. The doctor will explain how to do this, usually by gradually reducing the dosage to minimize withdrawal symptoms as much as possible. Withdrawal symptoms such as restlessness, difficulty sleeping, nervousness, agitation, anxiety, feeling your heartbeat (palpitations), high blood pressure, nausea or vomiting, diarrhea, tremor or sweating may occur if you stop taking this medicine abruptly.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cod Acamol may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects:

All medicines may cause allergic reactions, although serious allergic reactions are very rare.

Stop treatment and refer to the doctor or proceed to a hospital immediately if the following effects appear:

- Allergic reactions such as sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting the whole body)
- In rare cases, paracetamol may cause acute skin diseases, characterized by redness, rash, blisters, widespread skin injury.

Acute skin side effects may occur even if you have taken medicines containing paracetamol as an active ingredient in the past and you did not suffer from side effects.

If skin side effects occur, stop treatment and refer to a doctor immediately.

- Signs of blood system changes occur, such as: bleeding, bruising, easier development of inflammations.

The following side effects of Cod Acamol have been reported at the following frequencies:

Common side effects (occur in up to 1 in 10 users)

- Nausea and vomiting, constipation
- Faint feeling, dizziness, sleepiness
- Shortness of breath.

If these effects occur, lying down may relieve them.

Uncommon side effects (occur in up to 1 in 100 users)

Withdrawal symptoms:

When you stop taking Cod Acamol, you may experience withdrawal symptoms, which include: restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), high blood pressure, nausea or vomiting, diarrhea, shaking or sweating.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

- An excessive feeling of wellbeing, or depression
- Stomach pains, inflammation of the pancreas
- Small eye pupils, vision problems, headaches
- Slowing of the pulse
- Difficulty in passing urine
- Inability to empty the bladder
- Liver damage, especially in heavy drinkers
- Hearing loss
- Changes in blood cells, such as a low number of cells which fight infection and of cells which are involved in blood clotting
- Dependence and addiction (see section "How do I know if I am addicted to the medicine?")

How do I know if I am addicted to the medicine?

If you notice any of the following signs during treatment with Cod Acamol, it could be a sign that you have become addicted:

- You need to take the medicine for longer than advised by your doctor
- You feel you need to use more than the recommended dosage
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you tell your doctor.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

• **Avoid poisoning!** This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.

• **Store in a dry place, below 25°C.**

• Do not discard medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

microcrystalline cellulose, lactose monohydrate, gelatin, sodium starch glycolate, magnesium stearate, colloidal silicon dioxide, col. FD&C blue No. 1 lake 12%

What the medicine looks like and the contents of the package:

Cod Acamol tablets are round, flat, and light blue with white flakes, with beveled edges. Scored in half on one side and debossed with "IKA" on the other.

The package contains 10 tablets in a blister (tray).

Name of License Holder and Manufacturer and its Address:

Teva Israel Ltd., 124 Dvora Hanevi'a St., Tel Aviv.

This leaflet was revised in January 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

040.04.22978

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