

**PATIENT LEAFLET AS PER THE PHARMACISTS' REGULATIONS**

**(PREPARATIONS) 1986**

The medicine is dispensed with a doctor's prescription only.

## Codivis Capsules

Composition:

Each capsule contains:

Codine 30 mg

Phenyltoloxamine 10 mg

See section 6 for the list of excipients.

**Read the entire leaflet carefully before you start using the medicine.**

This leaflet contains essential information about the medicine. If you have any further questions, contact your physician or pharmacist. This medicine has been prescribed for you. Do not forward it 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 under the age of 12 years.

**Prescription opioids carry serious risks of addiction especially with prolonged use and they have a potential for misuse and overdose. An opioid overdose, often marked by slowed breathing, can cause death. Make sure you know the name of your medication, how much and how often to take it, the duration of treatment and its potential risks & side effects.**  
**Additional information about the risk of dependence and addiction can be found at:**  
[https://www.health.gov.au/Units/Office/HD/MTI/Drugs/risk/DocLib/opioids\\_en.pdf](https://www.health.gov.au/Units/Office/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf).

### 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for relief of cough.

Therapeutic group:

Codine is an opiate used as cough suppressant.

Phenyltoloxamine belongs to the antihistamine class.

### 2. BEFORE USING THE MEDICINE:

**Do not use the medicine if:**

- You are sensitive (allergic) to any of the active ingredients (codine, phenyltoloxamine) or any of the other components contained in the drug (see section 6).
- You are pregnant or breastfeeding.
- You suffer or have previously suffered from a benign tumor in the adrenal gland (pheochromocytoma), enlarged prostate, glaucoma, chronic constipation or severe respiratory problems.
- You are taking or have taken within the last two weeks, monoamine oxidase inhibitors (MAOI).
- You suffer from acute alcoholism.
- You suffer from severe diarrhea.
- You are at risk from a blocked intestine or have severe stomach cramps caused by a condition known as biliary colic.
- You have increased pressure on the brain, have just had a head injury or if you are unconscious.
- In children below the age of 12 years.
- You belong to the population of people who metabolise very rapidly codine into morphine.

**Special warnings regarding the use of this medicine:**

- **Do not use the medicine without consulting a physician prior to beginning treatment if you suffer or have previously suffered from:** Addiction to drugs (opioids) or medicines, Low blood pressure, Muscle weakness (myasthenia gravis), Epilepsy, convulsions, Severe deformities of the spine, Mental illness due to infections, Severe obesity, Gallbladder disease or stones in the gallbladder, Weakness and fatigue

**Do not use the medicine without consulting a physician prior to beginning treatment if you suffer or have previously suffered from impaired function of:** The respiratory system (asthma, bronchitis, emphysema), the heart (such as pulmonary hypertension and right ventricular hypertrophy - cor pulmonale), the liver, the kidney, gastrointestinal system (e.g. ulcer, colitis, enteritis, severe bloody diarrhea, blockage in the bow), thyroid, adrenal gland, prostate (for example, if you suffer from enlarged prostate gland and difficulty urinating).

Patients with poor renal function, elderly patients and children (above the age of 12) requiring medical follow up due to being more vulnerable to side effects should consult the physician prior to using this medicine.

Codivis is not recommended for children with respiratory problems. Do not administer Codivis to children and adolescents below the age of 18 after removal of their tonsils or adenoids due to Obstructive Sleep Apnea, since these patients are predisposed to respiratory problems more than others.

Naturally and rarely, in some people, codine is metabolized in the body more rapidly than in most people. In such rare cases, high levels of the metabolite may accumulate in their bodies, which may cause severe side effects such as: excessive sleepiness, confusion, shallow breathing, small pupils, nausea, vomiting, constipation or loss of appetite. In such cases, stop the treatment and seek medical treatment immediately.

In most cases, it is impossible to predict in advance whether the patient belongs to the group of people who are at risk of this effect. Prolonged use may cause dependence! Do not use this medicine frequently or for prolonged period of time without consulting a physician.

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.** In particular, inform your physician or the pharmacist if you are taking:

Medicines which affect the central nervous system (such as: tranquilizing drugs or sleeping tablets [e.g. diazepam, nitrazepam, temazepam]), medicines for Parkinson's disease, epilepsy, schizophrenia (e.g. chlorpromazine, haloperidol), Tricyclic antidepressants, Monoamine oxidase inhibitors (for the treatment of depression) or less than 2 weeks after the end of treatment. Medicines for the treatment of allergy, such as antihistamines. Medicines for the treatment of diarrhea, such as: loperamide, Medicine used to treat nausea and vomiting, such as: metoprolamide, domperidone, Cimetidine for the treatment of peptic ulcer and indigestion, Rilovair for the treatment of HIV. Anesthetics, especially for general anesthesia. Sodium oxybate for the treatment of narcolepsy. Quinidine or mexiletine for the treatment of arrhythmia. Medicines administered prior to a medical procedure (surgical) and after heart attack such as: atropine

**Use of this medicine and food**

Take the medicine with food.

**Use of the medicine and alcohol consumption**

Do not drink wine or alcoholic beverages during treatment with the medicine. Alcohol may enhance the side effects of the central nervous system such as: drowsiness.

**Pregnancy and breastfeeding**

Do not use the medicine if you are pregnant or breastfeeding.

**Driving and operating machinery:**

Use of this medicine may impair alertness and cause somnolence,

confusion, blurred or double vision. Therefore caution should be exercised when driving a car, operating dangerous machinery and in every activity demanding alertness. Children should be cautioned against riding a bicycle or playing near a road, etc.

**Smoking**

If you are a smoker - tell the physician prior to beginning treatment with this medicine.

**Important information about some of the medicine ingredients:** Each capsule contains about 16 mg lactose. Do not use it if you are sensitive to lactose.

**HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the physician's instructions.

You should check with the physician or the pharmacist if you are unsure. The dosage regimen will be determined only by the physician. The usual dosage is generally:

Adults and children above the age of 12 years: One capsule in the morning and in the evening

It is recommended to drink water after taking the medicine.

This medicine is not intended for babies and children under the age of 12 years.

If your condition has not improved within 3 days, stop the treatment and contact a physician.

Take the medicine with food.

**Do not exceed the recommended dose.**

Do not open and spread the capsule's content.

**If you took an overdose or by mistake a child swallowed this medicine,** go immediately to the emergency room of a hospital and take the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult your physician.

Persist with the treatment as recommended by the physician.

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 any further questions regarding the use of this medicine, contact your physician or the pharmacist.

**4. SIDE EFFECTS:**

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

**Stop using the medicine and contact a physician in the following cases:** Severe allergic reaction, the symptoms include: skin rash, itching, swelling mainly of the face, lips, tongue or throat, difficulties swallowing and/or breathing.

Physical and psychological dependence.

**Additional common side effects:** Drowsiness, Nausea and vomiting, Constipation, Sweating, Apart from constipation, these side effects tend to disappear with time.

**Additional uncommon side effects:** Drowsiness, Sensation of fainting while standing, Small pupils, Blurred vision, Double vision or other changes in vision, Glaucoma. Confusion and loss of consciousness, Mood changes such as depression, Feeling extremely happy for no particular reason. Hallucinations, Nightmares, Headache, Sensation of dizziness (vertigo), Facial flushing, Difficulty breathing, Stomach cramps, Sweating, Dry mouth, Pain or difficulty during urination, Passing less urine than usual, Biliary spasm (the

symptoms include: Causing pain in the right side of the abdomen, particularly after eating a meal, which may spread towards your right shoulder, Palpitations, Increased intracranial pressure, Abnormally high levels of glucose in the blood (hyperglycemia), Inflammation of the pancreas (pancreatitis), Feeling unwell, Tiredness, Decrease in body temperature (hypothermia), High fever, Enlarged spleen or swollen/enlarged lymph nodes, Anorexia, Weight gain, Uncontrolled muscle movements, Restlessness, Muscle rigidity, Faster or slower pulse, Skin rash, itching, (erythema), Reduced sexual drive or impotence, following long term use of the medicine, Blood ce diseases, Decreased blood pressure, Euphoria and tinnitus, Difficulties breathing.

If any side effect worsens, or if you suffer from a side effect not mentioned in the leaflet, you should consult your physician.

**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 of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from your physician.

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

• Store at a temperature below 25°C.

• Store in the original package.

**6. FURTHER INFORMATION:**

In addition to the active ingredients, the medicine also contains: Polyethylene Glycol 10,000, Lactose, Gelatin, Titanium Dioxide, Red Iron Oxide, Black Iron Oxide, Yellow Iron Oxide, Erythrosin. **What does the medicine look like and what are the contents of the package:**

Each capsule is composed of an opaque pink body and opaque brown head, and contains brown powder. Each pack contains blisters of 10 capsules. Quantity of capsules per pack: 8 or 10 capsules. Not all pack sizes may be marketed.

**Manufacturer/Registration Holder and address:**

CTS Chemical Industries Ltd., Kiyat Malachi

This leaflet was checked and approved by the Ministry of Health on: 06.2015

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132-46-23488-00

**كيفية بيئو الدواء وما هو محتوي العلبه:**

كل كبسولة من كوديفيس تتلّف من جسم زهري ومحمك ورأس بني محمك، وتحتوي على بودرة باللون البني. كل علبه تحتوي على بيسترات من 10 كبسولات. كمية الكبسولات في العلبه: 8 أو 10 كبسولات. قد لا تكون جميع أحجام العلب مسوّقه.

**المنتج/صاحب التسجيل وعنوانه:**

كريم للمصناعات الكيمياءية مرض، كريات ملاحي

فحصت هذه النشرة ورخصت من قبل وزارة الصحة بتاريخ: 06.2015

رقم سجل الدواء في سجل الأدوية الحكومي في وزارة الصحة:

132-46-23488-00

تمت صياغة هذه النشرة بلغة المنكر بهدف التبسيط وتسهيل القراءة.

لكن الدواء مخصص للخسنيين على حد سواء.

