

**Patient package insert according to
Pharmacist's Regulations (Preparations) - 1986**

This medicine can be sold by physician's prescription only

REKOD TABLETS, 20 mg

Each tablet contains:

Codeine Phosphate 20 mg.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

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

This medicine has been prescribed for 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.

Medicines of the opiate family may cause addiction, mainly upon prolonged use, and have a potential of misuse and overdose. The reaction to overdose can be manifested by slow breathing and even cause death.

Make sure you know the name of the medicine, the dose you take, administration frequency, treatment duration, side effects and potential risks.

Additional Information about the risk of dependence and addiction can be found in the following link:

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

Medicines that contain codeine shall be used only for the treatment of acute (short-term) mild to moderate pain in patients over the age of 12 years only; and only if the pain cannot be treated with analgesics such as paracetamol or ibuprofen, in light of the fact that the use of codeine may increase the risk of respiratory depression.

1. What is this medicine intended for?

This medicine is intended for the relief of mild to moderate pain and for the symptomatic relief of unproductive (dry) cough.

Therapeutic group: Analgesic, cough suppressant of the opiate group.

2. Before using this medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (codeine) or other ingredients from the opiate group, or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- You suffer from difficulty breathing, or other chronic lung disease.
- You are suffering or have suffered in the past from head injury, or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes).
- You are having an asthma attack.
- You suffer from liver failure.
- You are at risk of blocked intestines.
- You suffer from alcoholism.
- In children below 12 years of age.
- In adolescents aged 12 to 18 years after removal of tonsils or adenoids, due to Obstructive sleep apnoea.
- You are breastfeeding.
- You know that your body metabolizes codeine very rapidly into morphine.

Special warnings regarding the use of this medicine

Before using REKOD TABLETS, tell your doctor if:

- You suffer from disease in the adrenal glands (Addison's disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma).
- You suffer from inflammatory bowel disease, including severe bloody diarrhoea (pseudomembranous colitis).
- You suffer from gall bladder disease or gall stones.
- You have recently had surgery on your gastro-intestinal tract or urinary system.
- You suffer from an enlarged prostate gland and have difficulty urinating (in males).
- You suffer from epilepsy.
- You are elderly or frail.
- You suffer from asthma or breathing problems.
- You suffer from an underactive thyroid gland.
- You suffer from muscles weakness disease (myasthenia gravis).
- You suffer from low blood pressure or are in a state of shock.
- You are addicted or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- You have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- You feel you need to take more **REKOD TABLETS** to get the same level of pain relief, this may mean you are becoming tolerant to the effects of the medicine or becoming addicted to it. Speak to your doctor, who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

This medicine contains codeine. Codeine is transformed into morphine in the liver by an enzyme. Morphine is the substance that relieves pain and alleviates coughing symptoms. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities and it will not provide enough pain relief or relieve their cough. Other people are more likely to get serious side effects because a very high amount of morphine is produced.

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

Withdrawal Syndrome

Taking this medicine regularly, particularly over a long period of time, can lead to addiction. Your doctor will explain how long you should take the medicine, when it is appropriate to stop and how to do this safely.

Rarely, increasing the dose of this medicine may make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking the medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important not to stop taking the medicine suddenly, as this may increase your risk of experiencing withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or taking it more frequently may increase the risk of addiction. Overuse or misuse can lead to overdose and/or death.

Additional special warnings:

- **Do not take this medicine for a longer duration than your doctor recommends.**

- Using this medicine too often or for a long time may lead to addiction, which might cause you to feel restless and irritable when you stop taking the medicine.
- Taking a painkiller to relieve headaches too often or for too long can make them worse.

Children and adolescents:

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

This medicine is not intended for adolescents aged 12 to 18 years for relief of pain after removal of tonsils or adenoids, due to Obstructive sleep apnoea syndrome.

This medicine is not recommended for the treatment of cough and pain for adolescents aged 12-18 years, who suffer from respiratory problems, as they may be at increased risk of serious side effects in the event of morphine toxicity.

Codeine-containing medicines should only be used for the treatment of acute (short-term) pain of mild to moderate intensity, only in patients above the age of 12 years, and only if the pain cannot be treated with painkillers such as paracetamol or ibuprofen; in light the fact that the use of codeine may increase the risk of respiratory depression.

Drug interactions:

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

- Medicines to treat depression such as Monoamine oxidase inhibitors (MAOIs e.g. moclobemide, linezolid, selegiline. **REKOD TABLETS** should be avoided for two weeks after stopping the MAOI), or tricyclic antidepressants (e.g. amitriptyline).
- Ciprofloxacin (antibiotic).
- Anti-emetic medicines (metoclopramide, or domperidone).
- Antiarrhythmic medicines (mexiletine, or quinidine).
- Anti-diarrhoea medicines (loperamide, kaolin).
- Cimetidine (to treat stomach ulcers).
- Medicines used to treat high blood pressure.
- Antiviral medicines (such as ritonavir).
- Medicines to treat allergies (antihistamines) that can cause drowsiness.
- Anti-cholinergic medicines (such as atropine).
- Medicines that affect the nervous system (such as chlorpromazine, diazepam, temazepam).
- Anaesthetics.
- Opioid antagonists (such as: naloxone, naltrexone, buprenorphine).

Concomitant use of **REKOD TABLETS** 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. For this reason, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe **REKOD TABLETS** together with sedative medicines, the dose and duration of concomitant treatment should be limited by your doctor.

You should inform your doctor about all sedative medicines you are taking and strictly follow your doctor's dose recommendation. It is recommended that friends or relatives be informed so that they are aware of the signs and symptoms mentioned above. You should contact your doctor if these symptoms occur.

Use of this medicine and food

Swallow the medicine with or without food, and with a glass of water.

Use of this medicine and alcohol consumption

Do not drink wine or alcoholic beverages during the period of treatment with this medicine.

Pregnancy and breastfeeding:

Pregnancy

Do not take **REKOD TABLETS** if you are pregnant or think you might be pregnant, unless you have discussed this with your doctor and it has been determined that the benefits of treatment outweigh the potential harm to the baby. If you use **REKOD TABLETS** during pregnancy, your baby may develop dependence and experience withdrawal symptoms after birth, which may require treatment.

Breastfeeding

Do not use this medicine when you are breastfeeding, since codeine passes into breast milk and will affect your baby. Some women who are at increased risk of developing side effects at any dose, may have higher levels of codeine in their breast milk.

If any of the following side effects develop in you or your baby, stop taking this medicine and seek immediate medical advice: feeling sick, being sick, constipation, poor appetite, feeling tired or sleeping for longer than normal and slow or shallow breathing.

Driving and operating machines:

REKOD TABLETS may make you feel drowsy, confused or dizzy, cause fits, blurred or double vision, or to see things that are not there (hallucinations). Make sure you are not affected by the medicine before you drive or operate machines.

Speak with your doctor or pharmacist if you are not sure whether it is safe to drive while using the medicine.

Important information about some of the ingredients of this medicine

REKOD TABLETS contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult the doctor before starting treatment with this medicine.

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

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

Recommended dosage unless otherwise prescribed by the doctor:

For Adults, adolescents and children above 12 years of age:

1-2 tablets every 4 hours and not more than 6 tablets a day.

This medicine should not be taken for more than 3 days. If there is no improvement in your condition within 3 days, consult your doctor.

Do not exceed the recommended dose.

Method of administration:

Do not chew! Swallow the medicine with or without food, and with a glass of water.

There is no information regarding crushing, splitting and chewing the tablet.

If you have accidentally taken a higher dosage

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

Possible overdose symptoms include feeling or being sick, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate.

If you forgot to take the medicine

Do not take a double dose to make up for a forgotten dose. If you forgot to take the medicine at the designated time, take a dose as soon as you remember and then take the next dose at the regular time.

If you stop taking the medicine

Do not suddenly stop taking this medicine. Before stopping this medicine, discuss it with your doctor first. The doctor will explain how to do this, usually by reducing the dose gradually, in order to minimize withdrawal symptoms as much as possible. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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 on the use of this medicine, consult the doctor or pharmacist.

4. Side Effects:

As with any medicine, the use of **REKOD TABLETS** 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.

Talk to your doctor if you notice any of the following side effects, or if you notice any other effects not listed:

- **Allergic reaction:** skin rash or itchy skin, difficulty breathing, increased sweating, redness and flushed face.
- **The Gastrointestinal system:** constipation, feeling or being sick, dry mouth, abdominal pain (may be caused by spasm of the bile ducts).
- **Heart:** slow or fast heart rate, feeling your heartbeat (palpitations), low blood pressure, low blood pressure on standing.
- **The Urinary system:** pain and difficulty in urinating, decreased frequency of urination.
- **The Nervous system:** drowsiness, malaise, tiredness, dizziness, 'spinning' sensation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, tolerance to the medicine (the medicine has less effect) or dependence (suffer from withdrawal symptoms if the medicine is stopped too quickly, see in section 4 "Drug Withdrawal").
- **Psychiatric effects – unknown frequency:** dependence and addiction (see in section 4 "How do I know if I am addicted to the medicine?"), mood changes, depression, hallucinations, restlessness, excitement, nightmares, confusion.
- **Eyes:** blurred vision or double vision, extremely small pupils.
- **Others:** muscle stiffness, decreased in sex drive, difficulty breathing, low body temperature.

Drug Withdrawal

Stop taking **REKOD TABLETS** may cause you to suffer from drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, increased blood pressure, feeling your heartbeat (palpitations), feeling or being sick, diarrhoea, shaking, shivering or sweating.

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

If you notice any of the following signs whilst taking **REKOD TABLETS**, it could be a sign that you have become addicted:

- You feel that you need to take the medicine for longer than advised by your doctor.
- You feel you need to use more than the recommended dose.
- 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 a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects problems associated with medications and drugs" on the Ministry of Health homepage (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in a dry place, below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information:

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

Starch, Lactose, Talc, Powdered Cellulose (Elcema), Gelatin, Magnesium Stearate, Purified Water.

What the medicine looks like and what the package contains:

Blister that contains white round biconvex tablets, with REKAH engraved on one side, plain on the other side.

Approved package sizes: 10 and 30 tablets.

Not all package sizes may be marketed.

Manufacturer and registration holder:

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St. Holon, 5881904, Israel.

Revised in December 2024 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

022-09-20913-00