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

This medicine is dispensed with a doctor's prescription only

REKOD TABLETS 20mg

Active Ingredient: Codeine Phosphate 20 mg

For the list of inactive ingredients: See section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. **If you have any further questions, please contact 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 illness is similar.

This medicine is not intended for children below 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. More information about the risk of dependence and addiction can be found in this link:
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf

Clarification regarding treatment for pain: Medicines that contain codeine may only be used for the treatment of acute pain (which lasts for a short period of time), of low to moderate intensity, in patients over the age of 12 only; and only if the pain can not be treated with painkillers such as paracetamol or ibuprofen. This is 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 dry cough

Therapeutic group: Opioid analgesic, cough suppressant.

2. Before using this medicine:

Do not use this medicine if:

- You are sensitive (allergic) to codeine or other opioids, or to any of the other ingredients contained in this medicine.
- You are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g. asthma, during asthma attack, bronchitis, and chronic lung disease), heart failure due to chronic lung disease, liver failure, head injury, intracranial pressure, intestinal obstruction, alcoholism, diarrhea resulting from poisoning or antibiotics.
- You are taking antidepressants of the monoamine oxidase inhibitors (MAOI) class (such as selegiline, rasagiline) or during the 14 days after their discontinuation.
- **Codeine should not be used in children over 12 years and below 18 years old** after tonsillectomy or adenoidectomy surgeries for the treatment of sleep obstructive apnea, since these patients are more prone to suffer from respiratory problems than other people.
- You are breastfeeding.
- **In children under 12 years old.**
- The medicine is not intended for people known to produce a significant amount of morphine from a codeine dose (who belong to the group of ultra rapid metabolizers), since they are at increased risk of experiencing severe side effects while using codeine.

Do not take this medicine without consulting a doctor before starting treatment:

- If you are pregnant.
- If you are suffering, or have suffered in the past, from impaired function of: the heart and/or vascular system, the liver, the kidney/urinary tract, the digestive system (e.g. ulcer, colitis, intestinal inflammation, severe bloody diarrhea), the thyroid gland, the prostate gland (for example, if you are suffering from prostatic hypertrophy and difficulty upon urination), Addison's disease, gallbladder disease or gallbladder stones, convulsions, epilepsy, weakness of the muscles (myasthenia gravis), hypotension or a situation of shock, addiction to drugs or medicines, psychiatric disease.

Special warnings related to the use of this medicine:

This medicine is not recommended for the treatment of cough or pain in children and adolescents aged 12-18 who suffer from respiratory problems.

Medicines that contain codeine may only be used for the treatment of acute pain (which lasts for a short period of time), of low to moderate intensity, in patients over the age of 12 only; and only if the pain cannot be treated with other painkillers such as paracetamol or ibuprofen; this, in light of the fact that the use of codeine may increase the risk of respiratory depression.

Naturally and rarely, in some people codeine undergoes metabolism (degradation) more rapidly than in most people. In these cases, high levels of metabolites may accumulate and cause severe side effects, such as: excessive drowsiness, confusion or shallow breathing. In such cases the patient should be referred immediately for medical care. In most cases it is impossible to know in advance whether a patient belongs to this risk group.

Prolonged use may cause dependence! Do not use this medicine frequently, or for a long period, without consulting a doctor.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Elderly patients are more susceptible to the effects of the medicine. Inform your doctor that you are taking this medicine before undergoing any kind of surgery (including dental surgery) or emergency treatment.

Taking a medicine for headaches too often or for too long can make them worse.

If you are taking or have recently taken other medicines including over the counter drugs and food supplements, inform the doctor or pharmacist. Especially, inform your doctor or pharmacist if you take:

- Drugs affecting the central nervous system: sedatives, hypnotics, drugs for parkinsonism, drugs for epilepsy, such as benzodiazepines, barbiturates, antidepressants - monoamine oxidase inhibitors (you can take codeine only 14 days after interrupting the treatment with medicines of this group).
- Tricyclic antidepressants.
- Alcohol.
- Medicines to treat allergies (antihistamines).
- Opioid antagonists (naloxone, naltrexone, buprenorphine).
- Anesthetic agents for surgery.
- Narcotic analgesics.
- Anti-cholinergic medicines (atropine).
- Anti-diarrhoea medicines (loperamide or kaolin).
- Anti-emetic medicines (metoclopramide or domperidone).
- Medicines used to treat high blood pressure.

- Ciprofloxacin (antibiotic).
- Antiarrhythmic medicines (quinidine).
- Cimetine (to treat stomach ulcers).
- Antiviral medicines (such as ritonavir).

Use of this medicine and food:

Do not chew! Swallow the medicine with food or water.

Use of this medicine and alcohol consumption:

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

Pregnancy and breastfeeding: Do not take this medicine during pregnancy, unless instructed by your doctor. **Do not use this medicine if you are breastfeeding**, since codeine passes into breast milk and may harm the baby.

Driving and operating machinery: Do not drive or use machinery during the use of this medicine before you make sure that you are not affected by this medicine, since it may cause you feel drowsy, confused or dizzy, blurred or double vision or hallucinations.

Use of this medicine and smoking: If you are a smoker, inform your doctor before commencing treatment with this medicine. Important information on some of Rekod's ingredients: Each tablet contains 20.4 mg of lactose. Do not use if you are allergic to lactose.

3. How should this medicine be used?

Always use according to the doctor's instructions. Consult the doctor or pharmacist if you are not sure.

Recommended dosage unless otherwise prescribed by your doctor:

Adults, adolescents and children over the age of 12:

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

Do not exceed the recommended dosage.

This medicine is not intended for administration to children under the age of 12 years.

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

If there is no improvement in your condition within 3 days, consult your doctor.

If you forgot to take this medicine at the scheduled time, take the dose as soon as you remember, but never take two doses at the same time.

Adhere to the treatment as recommended by the doctor.

Do not chew! Swallow the medicine with food or water.

Do not take this medicine with alcohol.

There is no information available regarding the crushing, splitting, or chewing of the tablet.

If you forgot to take this medicine - do not take a double dose.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, immediately contact a doctor or go to a hospital emergency room and bring the package of the medicine with you. **Possible overdose symptoms:** drowsiness, weakness, tiredness, dizziness, vomiting, nausea, perspiration, confusion, low blood pressure, pinpoint pupils, slow breathing rate, fast heart rate.

If you stop taking the medicine after prolonged use, you may develop withdrawal symptoms such as: tremor, sweating, increased heart rate and breathing rate, increased blood pressure, insomnia, restlessness, irritability, anxiety, depression, anorexia, diarrhoea, excessive tearing, runny nose, sneezing, yawning, fever, weakness, muscle cramps, dehydration.

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

4. Side Effects:

Like any medicine, the use of Rekod may cause side effects in some users. Do not be alarmed while reading the list of side effects; you may not suffer from any of them. Dryness of the mouth, constipation, nausea, vomiting, drowsiness, gastrointestinal disturbances.

Stop the treatment and contact the doctor in the following cases:

- **Allergic reaction (rare):** skin rash with itchy skin (urticaria), difficulty breathing, increased sweating; redness, swelling principally in face and throat; faintness.
- **Ophthalmic:** blurred or double vision, constriction of the pupils (pinpoint pupils).
- **Urinary system:** pain and difficulty in passing urine and urinary retention.
- **Nervous system:** excessive drowsiness, weakness, tiredness, dizziness, vertigo, seizures, convulsions, increased intracranial pressure (pain in the eyes, changes in vision or headache between the eyes), headache, tolerance to the medicine (the medicine has less effect).
- **Psychiatric effects:** mood changes, depression, hallucinations, nervousness, restlessness, excitement, nightmares, confusion, excitement.
- **Heart:** change in heart rate, palpitations or irregular heart rate, low blood pressure, a drop in blood pressure upon standing up from a lying position.
- **Others:** muscle stiffness, decreased in sex drive, difficulty breathing, low body temperature.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Side effects and drug interactions in adolescents and in children over the age of 12: Parent must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child. See special side effects and drug interactions specified above.

Side effects may be reported to the Ministry of Health by clicking the link "Report of side effects resulting from the use of medicines" on the homepage of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects.

5. How should this medicine be stored?

- **Avoid poisoning!** This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a 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.
- Store below 25°C in a dry place.

6. Further information:

In addition to the active ingredient the medicine also contains: Starch, Lactose, Gelatin, Magnesium stearate, Talc, Powdered cellulose (Elcema).

What does the medicine look like and what is the content of the package: A white round tablet, REKAH engraved on one side, plain on the other. 10 tablets in a blister PVC-ALU.

License Holder and Manufacturer: Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St. Holon, Israel.

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