**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**
This medicine is dispensed without a doctor's prescription

# Rokacet® Caplets

**Active ingredients:**

Each caplet contains:

| | |
|---|---|
| paracetamol | 500 mg |
| caffeine | 30 mg |
| codeine phosphate | 10 mg |

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

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

Use the medicine according to the instructions in the section about dose in this leaflet.

Consult the pharmacist if you need further information. Contact your doctor if the disease symptoms worsen or do not improve after 3 days.

**Taking this medicine with medicines of the benzodiazepine family, medicines suppressing the central nervous system (including drugs) or alcohol may cause a sensation of deep somnolence, difficulties breathing (respiratory depression), coma and death.**

**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 may even cause death.**
**Make sure that 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 is available in the following link:**
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_he.pdf

## 1. What is this medicine intended for?

The medicine is intended for relief of pain and cough and for reduction of fever accompanied by pain.

**Therapeutic group:**

Paracetamol: analgesic, antipyretic.

Codeine: analgesic of the opiates group.

Caffeine: xanthine derivative, assists in pain relief.

## 2. Before using this medicine

**Do not use this medicine:**

- If you are sensitive (allergic) to paracetamol, caffeine, codeine, other opioid analgesics or to any of the other ingredients in this medicine (see section 6).
- If you are taking other medicines containing paracetamol or codeine.
- In children below the age of 12.
- In adolescents above the age of 12 and below the age of 18 after surgery for removal of tonsils or adenoids due to obstructive sleep apnea.
- If you know that your body metabolizes codeine into morphine very rapidly.
- If you are breastfeeding.

**Special warnings about using this medicine**

**Before treatment with Rokacet, tell your doctor if:**

- You have liver or kidney disease, including alcoholic liver disease.
- You have bowel problems, including bowel obstruction.
- You have undergone gallbladder removal surgery.
- You are or have ever been addicted to opioids, alcohol, prescription medicines or drugs. Tell your doctor or pharmacist.

**Additional warnings:**

- If you have previously developed cutaneous side effects due to taking products containing paracetamol, do not take products containing paracetamol to avoid recurrent severe cutaneous effects.
- This medicine contains codeine. Codeine is transformed into morphine in the liver by an enzyme. Morphine has an analgesic effect. Some people have a variant of this enzyme, which can have various effects. In some people, morphine is not produced or is produced in very small quantities, and the pain relief effect will be insufficient. Other people are more likely to experience serious side effects due to production of a very high amount of morphine. If you experience any of the following side effects, **you must stop taking this medicine and seek immediate medical assistance**: slow or shallow breathing, confusion, sleepiness, small pupils, nausea or vomiting, constipation, lack of appetite.
- Codeine can cause addiction if you take it continuously for more than 3 days. This can cause symptoms of withdrawal from the medicine when you stop taking it.
- Taking codeine regularly for a long time may lead to addiction and misuse, which may result in overdose and/or death.
- Taking an analgesic, including this medicine, for headaches for more than 3 days continuously can exacerbate the pain.
- Do not take the medicine longer than needed.

**Children and adolescents**

Do not use in children below the age of 12.

Use in adolescents (12-18) **after surgery**:

Codeine should not be used for pain relief in adolescents after surgery for removal of tonsils or adenoids due to obstructive sleep apnea.

Use in adolescents **with breathing problems**:

Codeine is not recommended for adolescents with breathing problems, since the symptoms of morphine toxicity may be more severe in these adolescents.

**Drug interactions**
**If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.** Particularly if you are taking:

- domperidone or metoclopramide (for nausea and vomiting).
- cholestyramine (to reduce blood lipid levels).
- phenothiazines (antipsychotics and antiemetics).
- benzodiazepines (for relief of anxiety states or for sleep induction)
- antidepressants of the MAO inhibitors (monoamine oxidase inhibitors) family within the last 2 weeks.
- medicines causing drowsiness (such as sedatives, antidepressants or alcohol).
- If you take blood thinning medicines (warfarin or other anticoagulants) and you need an analgesic on a daily basis, consult your doctor because of the risk of bleeding. But you can still occasionally take Rokacet together with anticoagulants.
- Do not take other medicines containing paracetamol, caffeine or codeine.

**Using this medicine and food**
The medicine can be taken with or without food.

Avoid consuming too much caffeine in drinks like coffee and tea when taking this medicine. High caffeine intake may cause sleeping problems, shaking and a sensation of discomfort in the chest.

**Using this medicine and alcohol consumption**
Using the medicine along with alcohol consumption may increase the hypnotic effect of the medicine.

**Pregnancy and breastfeeding**
Talk to your doctor before taking Rokacet if you are pregnant.
Do not take Rokacet if you are breastfeeding. Codeine and morphine pass into breast milk.

**Driving and using machines**
Using this medicine may affect your ability to drive, as the medicine may cause sleepiness or dizziness. Do not drive while taking this medicine until you know how it affects you. Contact your doctor or pharmacist if you are not sure whether you can drive while using this medicine.

**Important information about some of this medicine's ingredients**
Rokacet contains less than 1 mmol (23 mg) sodium per caplet, therefore it is considered essentially "sodium free".
Rokacet contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

## 3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine

**The recommended dosage is usually:**

Adults:
2 caplets every 4-6 hours as needed.
Take at intervals of at least 4 hours between the doses.
Do not exceed the dose of 8 caplets in 24 hours.

Adolescents aged 16 -18 years:

1-2 caplets every 6 hours as needed.

Take at intervals of at least 6 hours between the doses.

Do not exceed the dose of 8 caplets in 24 hours.

Adolescents aged 12 -15 years:

1 caplet every 6 hours as needed.

Take at intervals of at least 6 hours between the doses.

Do not exceed the dose of 4 caplets in 24 hours.

**Do not exceed the recommended dose.**

Do not chew, spilt or crush! Swallow the medicine with plenty of water.

Do not hold the medicine in the mouth beyond the time required to swallow it.

Do not give this medicine to babies and children below the age of 12 years due to the risk of severe breathing problems.

Do not use this medicine frequently or for a long period of time (more than 3 days) without consulting a doctor.

**Withdrawal symptoms**

This medicine contains codeine and may cause addiction if you take it continuously for more than 3 days. When you stop using the medicine, you may experience withdrawal symptoms. You should talk to your doctor or pharmacist if you think you are suffering from withdrawal symptoms.

**Warning signs of addiction**

If you take the medicine according to the instructions in the leaflet, it is unlikely that you will become addicted to the medicine. However, if any of the following apply to you, it is important that you contact your doctor:

- You feel a need to take the medicine for longer periods of time.

- You feel a need to take doses higher than the recommended doses of the medicine.

- When you stop taking the medicine, you feel very unwell, but you feel better if you start taking the medicine again.

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

You should do this even if you feel well, because too much paracetamol may cause delayed serious liver damage.

If the symptoms continue or the headache becomes persistent, contact your doctor.

**If you forget to take the medicine**, do not take a double dose. Take the next dose at the usual time and consult your doctor.

**Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## 4. <u>Side effects</u>

Like with all medicines, using Rokacet may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

**Stop using this medicine and contact your doctor immediately if you experience:**

- Severe abdominal pain, dry mouth, nausea and vomiting if you have undergone gallbladder removal surgery.
- Nervousness, dizziness, irritability, excessive drowsiness or restlessness.
- Allergic reactions which may be severe, such as skin rash and itching, sometimes with swelling of the mouth or face or shortness of breath.
- Skin rash, peeling or mouth ulcers; itching or sweating.
- Breathing problems, especially if you have experienced them previously while using other analgesics, such as ibuprofen and aspirin.
- Unexplained bruising or bleeding.
- Nausea, upset stomach, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Difficulty urinating.
- Paracetamol may rarely cause occurrence of acute skin diseases, the signs of which can be: redness, rash, blisters, extensive skin injury. Acute cutaneous side effects may appear even if you have previously taken products containing the active ingredient paracetamol with no problem. If cutaneous side effects occur, stop the treatment and contact your doctor immediately.

**Additional side effects**

- Constipation.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Reporting side effects**
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

## 5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions**: Store below 25˚C.

## 6. Additional information

- **In addition to the active ingredients, this medicine also contains:**
stearic acid, Opadry OY-L-28990 (lactose, hypromellose, polyethylene glycol), sodium starch glycolate, Opadry Yellow-31F32864 (lactose, hypromellose, titanium dioxide, polyethylene glycol, D&C yellow #10 lake, iron oxide yellow and iron oxide red).

- **What the medicine looks like and contents of the pack:**
Yellow, oblong, biconvex film-coated caplets imprinted with "TARO" on one side of the caplet. The caplets are packed in blisters, in carton packages of 4 and 20 caplets. Not all pack sizes may be marketed.

- **Manufacturer's and Registration Holder's name and address:**
Taro Pharmaceutical Industries Ltd.,
14 Hakitor St., Haifa Bay 2624761.

Revised in July 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
027-84-21960-00