

Patient package insert in accordance with the Pharmacists' Regulations (Preparations)
- 1986

This medicine is dispensed with a doctor's prescription only

Rokacet® Plus Caplets

Composition:

Each caplet contains:

Paracetamol 500 mg

Caffeine 50 mg

Codeine 15 mg
phosphate

For the list of inactive ingredients and allergens in this medicine see section 2 'Important information about some of this medicine's ingredients', and 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, consult your doctor or pharmacist.

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

- Medicines containing codeine should only be used to treat acute pain (of short duration) of moderate intensity in patients over 12 years old and only if the pain cannot be treated with pain relievers such as paracetamol or ibuprofen. This is due to the fact that use of codeine may increase the risk of respiratory depression.
- This medicine contains codeine, which can cause addiction when taken for more than 3 consecutive days. This can lead to withdrawal symptoms from the medicine, when its use is discontinued.
- Taking an analgesic for headaches for more than 3 consecutive days can aggravate the pain.
- Naturally and rarely, in certain people, codeine is metabolized (broken down) more rapidly than in the majority of the population. In these rare cases, high levels of the metabolite may accumulate and cause severe side effects, such as: excessive drowsiness, confusion or shallow breathing. In these cases, immediately refer the patient for medical treatment.
In most cases, it is impossible to know in advance whether the patient belongs to the group of people at risk for this effect.

Taking this medicine with benzodiazepines, medicines which suppress the central nervous system (including narcotic drugs) or alcohol may cause deep drowsiness, breathing difficulties (respiratory depression), coma, and death.

Opiate medicines can cause addiction, especially with prolonged use, and they have the potential for misuse and overdose. An opioid overdose is often marked by slowed breathing and can cause death.

Make sure you know the name of the medicine you are taking, how much and how often to take it, the duration of treatment, and its side effects and potential risks.

To find out more about the risk of dependence and addiction follow this link:
https://www.health.gov.au/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf

1. What is this medicine intended for?

This medicine is intended to relieve pain, relieve cough, and reduce fever accompanied by pain.

Therapeutic group

Paracetamol: analgesics, antipyretics.

Codeine: opiate analgesic.

Caffeine: a xanthine derivative, helps relief pain.

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 that this medicine contains. See section 6 'Additional information' for a list of inactive ingredients.
- If you are breastfeeding.
- In children under 12 years old.
- In adolescents over 12 years old and under 18 years old after surgical removal of their tonsils or adenoids due to obstructive sleep apnea, as these patients are more prone than others to suffer from respiratory problems resulting from administration of codeine.
- If you are taking other medicines containing paracetamol or codeine.
- If you are suffering from respiratory depression.
- In people known to produce a significant amount of morphine from a dose of codeine (people belonging to the ultra-rapid metabolizers group, whose bodies metabolize codeine to morphine at a faster rate than normal), as they are at increased risk of suffering from severe side effects when using codeine.

Special warnings regarding use of this medicine

Before treatment with Rokacet Plus, inform your doctor if:

- You suffer, or have suffered in the past, from impaired function of: the heart and/or blood vessels, the liver, including alcoholic liver disease, the kidney/urinary tract, the digestive system (such as inflammatory bowel diseases or peptic ulcer, blockage of your bowel).
- You have undergone an operation to remove your gall bladder.

Additional warnings:

- If you have developed skin side effects in the past as a result of taking medicines containing paracetamol, do not take medicines containing paracetamol, so that severe skin reactions will not recur.
- This medicine is not recommended for treating cough and cold in children and adolescents between the ages of 12-18 who have respiratory problems.
- Use for more than 3 consecutive days may cause dependence!
- Paracetamol may cause liver damage when:
 - given at a higher dose than recommended.
 - given for an extended period.
 - drinking alcoholic beverages during the course of treatment.
 - taking additional medicines that affect liver function.
- Do not take additional fever reducers and pain relievers or cold medicines without consulting a doctor or pharmacist - to prevent paracetamol overdose/toxicity.
- Do not use this medicine often or for a prolonged period (more than 3 days) without consulting a doctor.
- Switch slowly from a lying or sitting position to standing. If you feel dizzy or nauseated, lie down and rest for a few minutes.
- Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces the pain relief. 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. Other people are more likely to get serious side effects because a very high amount of morphine is produced .
If you experience any of the following side effects, you must stop taking this medicine and seek immediate medical help: slow or shallow breathing, confusion, sleepiness, small pupils, nausea or vomiting, constipation, lack of appetite.

Drug interactions

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

- medicines affecting the central nervous system (such as: sedatives, hypnotics, medicines for Parkinson's, for depression, anti-epileptics, or alcohol).
- warfarin or other anticoagulants. If you are taking warfarin, you can take Rokacet Plus from time to time, but consult a doctor before taking Rokacet Plus regularly because of the risk of bleeding.
- MAO (monoamine oxidase) inhibitor antidepressants in the last two weeks.

- other fever reducers and pain relievers. Do not take other medicines containing paracetamol, caffeine or codeine.
- domperidone or metoclopramide for nausea or vomiting (may increase the pain relieving effect of paracetamol).
- cholestyramine to lower blood lipid levels (may reduce the pain relieving effect of paracetamol).

Using this medicine and food

Do not drink large quantities of coffee, tea or cola (or other caffeine-containing products) during the course of treatment with the medicine. High levels of caffeine may cause sleep problems, tremor and chest discomfort.

Using this medicine and alcohol consumption

Use of this medicine with alcohol consumption may increase the sleep-inducing effect of the medicine.

Pregnancy and breastfeeding

Talk to your doctor before taking Rokacet Plus if you are pregnant.

Do not take Rokacet Plus if you are breastfeeding. Codeine and morphine pass into breastmilk.

Use in the elderly

Elderly patients may need a reduced dose.

Children and adolescents

Do not use in children under 12 years old.

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

Do not use codeine for pain relief in adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnea Syndrome.

Use in adolescents **with breathing problems**:

Codeine is not recommended in adolescents with breathing problems, since the symptoms of codeine toxicity may be worse in these adolescents.

Driving and using machines

Use of this medicine may impair alertness and cause dizziness and, therefore, requires caution when driving a car, operating dangerous machines and when engaging in any activity requiring alertness.

Important information about some of this medicine's ingredients

Each caplet contains 0.27-0.40 mg sodium.

This medicine contains lactose and may cause sensitivity in patients sensitive to lactose.

3. How to use this medicine?

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dose is usually:

One caplet 3-4 times a day.

For severe pains - 2 caplets 3-4 times a day.

Do not exceed a dosage of 8 caplets in 24 hours.

Do not exceed the recommended dose.

Do not chew, split or crush! Swallow the medicine with a lot of water.

Do not hold the medicine in your mouth for longer than the time required to swallow it.

Do not give this medicine to infants and children under 12 years old.

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

Withdrawal syndrome

This medicine contains codeine and may cause addiction if you take it for more than 3 consecutive days. When you stop using the medicine, you may feel withdrawal syndrome. Talk with a doctor or pharmacist if you think you are suffering from withdrawal syndrome.

Warning signs of addiction

If you take this medicine according to the instructions in this leaflet, you are unlikely to become addicted to this medicine. Nevertheless, if any of the following applies to you, it is important to consult your doctor.

- you feel the need to take this medicine for longer periods.
- you feel the need to take higher doses than the doses recommended for this medicine.
- when you stop taking this medicine you feel very unwell, but you feel better if you start taking it 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 must do this even if you feel well, because too much paracetamol can cause delayed, serious liver damage.

If your symptoms continue or your headache becomes persistent, see your doctor.

If you forget to take this medicine at the required time, 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 the dose each time 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. Side effects

As with any medicine, use of Rokacet Plus may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Discontinue use and consult a doctor immediately if the following occur:

- Severe abdominal pain, dry mouth, nausea and vomiting if you have recently undergone an operation to remove the gall bladder.

- Nervousness, dizziness, irritability, excessive drowsiness or restlessness.
- An allergic reaction which may be severe, such as skin rash and itching.
- Skin rash or peeling or mouth ulcers; itching or sweating.
- Breathing problems, especially if they occurred with past use of other pain relievers, such as ibuprofen and Aspirin.
- Nausea, indigestion, sudden weight loss, loss of appetite and yellowing of the skin and eyes.
- Difficulty passing urine.
- Paracetamol may, in rare cases, cause severe skin diseases, whose signs can include: redness, rash, blisters, widespread skin damage. Severe skin side effects may occur even if you have had no problem in the past taking medicines containing paracetamol as the active ingredient. If skin reactions occur, discontinue the treatment and consult your doctor immediately.

Additional side effects

- Constipation.

If you experience a 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 Medication' 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 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) 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, the medicine also contains:
Polyvinylpyrrolidone, pregelatinised starch, sodium starch glycolate, stearic acid, lactose, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol, FD&C yellow #6 lake.

Each caplet contains 0.27-0.40 mg sodium.

This medicine contains lactose and may cause sensitivity in patients sensitive to lactose.

- What the medicine looks like and what are the contents of the package:

Light orange caplets with “TARO” imprinted on one side of the caplet. The caplets are packaged in blisters, in cartons of 2, 10, 12, and 24 caplets.
Not all pack sizes may be marketed.

- Manufacturer and registration holder:
Taro Pharmaceutical Industries Ltd.,
14 Hakitor St., Haifa Bay 2624761.

Revised in March 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health National Drug Registry:
4048.25715