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

This medicine is dispensed without a doctor's prescription

RAZAMOL 500 mg Suppositories

The active ingredient:
Each suppository contains:
Paracetamol 500 mg.

For information on inactive ingredients and allergens in the medicine – see section 6 "additional information".
Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
Take the medicine according to the instructions in the section about dose in this leaflet – section 3 – "HOW SHOULD YOU USE THE MEDICINE?".
Consult a pharmacist if you need further information.
Ask your doctor if symptoms worsen or do not improve.
The medicine is intended for adults and children over the age of 12 years.
You should consult a doctor if the fever lasts more than 3 days or if the symptoms do not pass within 5 days despite the use of the medicine.

1. WHAT IS THE MEDICINE INTENDED FOR?

This medicine is used for pain relief and fever reduction.

Therapeutic group:
Analgesic and antipyretic.

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:
- You have a known sensitivity to any of the ingredients of the medicine.
- You have a severe active liver disease.

Specials warnings regarding the use of this medicine:
- If you have previously developed cutaneous side effects as a result of taking medicines containing paracetamol, do not take paracetamol containing medicines.
- If you know of any food or medicine sensitivity, inform your doctor.
- The medicine contains paracetamol that may cause liver damage in the following cases: when the administered dose is higher than recommended, when used for extended periods, when consuming alcoholic beverages during the treatment period, when taking other medicines that affect the liver, when suffering from chronic malnutrition.
- Avoid taking high doses (within the recommended limits) of this medicine while fasting.
- Do not take other fever reducing and pain-relieving medicines, or other cold medicines without consulting a doctor or a pharmacist - to prevent paracetamol overdose/toxicity.
- Do not take other medicines containing paracetamol while using this medicine.
- Avoid alcohol consumption or medicines containing alcohol while using this medicine.

Before using Razamol 500 mg inform your doctor if:
- You are pregnant or breastfeeding.
- You suffer or have suffered in the past from: impairment of liver function or kidney/urinary tract; alcoholism; jaundice.

Drug interactions
If you are taking, or have recently taken, other medicines including non-prescription medicines and dietary supplements, inform your doctor or pharmacist.
In particular if you are taking:
- Anticoagulants, particularly warfarin.
- Medicines against convulsions/epilepsy (carbamazepine, phenytoin, phenobarbital).
- Barbiturates.
- Rifampicin.
- Isoniazid, Zidovudine (for AIDS patients).
- NSAID medicines.
- Metoclopramide or domperidone (used to treat nausea, vomiting and other digestive problems).
- Chloramphenicol (antibiotic).
- Probenecid (to treat gout).
- Cholestyramine (to reduce hyperlipidemia).
- Other analgesic or antipyretics.

Using paracetamol with alcohol:
Do not consume alcohol during treatment with paracetamol because of the increased risk of liver damage.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, consult your doctor or pharmacist before using this medication.

Children and adolescents:
This medicine is intended for adults and children over the age of 12 years.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are not sure about the dosage and method of treatment of the medicine.

The usual dose is generally:
Adults and children aged 12 years and older:
1-2 suppositories every 4-6 hours as needed, up to 8 suppositories per day.

Do not exceed the recommended dose.
You should consult a doctor if the fever lasts more than 3 days or if the symptoms do not pass within 5 days despite the use of the medicine.
- Do not swallow.
- For external use only.
- Do not halve the suppository.

Instructions for use:
How to insert the suppository:
1. First, wash your hands well.
2. Remove the suppository wrapper and moisten with water.
3. Lie on your side. Push the suppository as deep as you can into the rectum with your finger. If the suppository is too soft to allow its insertion, chill it in the refrigerator for 30 minutes or place it under a stream of cold water before removing the wrapper.
4. Wash your hands after inserting the suppository.

If you accidentally taken a higher dosage
If you took an overdose or if a child accidentally swallowed the medicine, proceed immediately to the doctor or to the emergency room of a hospital, and bring the medicine package with you.
Do not induce vomiting unless explicitly instructed by your doctor! Even if you feel well, immediate treatment is essential **due to the risk of severe liver damage.**
Side effects can be nausea and vomiting, diarrhea, loss of appetite, abdominal pain, bloating, increased sweating, pain or tenderness in the upper abdomen and they may not reflect the severity of liver damage.

If you forget to take the medicine:
If you forget to take this medicine at the required time, take the next dose as soon as you remember, but if it's almost time for the next dose, do not take a double dose. Take your next dose at the usual time and consult the doctor.

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 regarding the use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS:

Like with any medicine, the use of Razamol 500 mg may cause side effects such as redness or rectal burning/pain or dizziness in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Severe side effects
Discontinue the use of the medicine and contact your doctor immediately if:
- Severe allergic reactions occur, such as rashes and itching, swelling of the face, lips, tongue, throat and/or limbs, which may cause breathing or swallowing difficulties.
- Paracetamol can cause in rare cases the appearance of acute skin diseases whose signs can be: redness, rashes, blisters, extensive skin damage.

Severe skin side effects may occur even if in the past you have taken medicines containing the active ingredient paracetamol without a problem.
If skin side effects occur, discontinue treatment and contact your doctor immediately.
- Nausea, vomiting, constipation, headache, irritability, liver damage, lung damage (rare) appeared.
- Appeared signs of changes in the circulatory system, such as: bleeding, bruising, inflammation develops more easily.

If a side effect occurs, if any of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult your doctor.

Reporting side effects:
Side effects can be reported to the Ministry of Health by clicking the link "report side effects due to medication" that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to an online form for reporting side effects, or by clicking the link:
https://sideeffects.health.gov.il.

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other 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 by the doctor.
- Do not use this medicine after the expiry date (exp. Date) stated on the package. The expiry date refers to the last day of that month.
- **Storage Condition**: Store below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Hard fat (Witepsol H15)

What the medicine looks like and what is the content of the package:
Oval milky-white suppositories.
Package contains 10 suppositories.

Marketing authorization holder and importer:
Raz Pharmaceuticals Ltd, 31 Gesher haetz Street, Emek Hefer Industrial Park, Israel.

Drug registration number at the national drug registry of the Ministry of Health:
156-32-34427-00

This leaflet was checked and approved by the Ministry of Health in June 2016

RAZP3049-01

Razamol PIL PB0524-03