

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 the list of inactive ingredients see section 6.

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

This medicine was prescribed to you. Do not forward it to others. It may harm them, even if it seems that they have a similar medical condition.

Use the medicine correctly. Ask your doctor if symptoms worsen or do not improve.

The medicine is intended for adults and children over the age of 12 years.

Refer to your doctor if fever persists for more than 3 days or if symptoms persist 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.

Special warnings regarding the use of this medicine:

- If you have previously developed cutaneous side effects as a result of taking preparations containing paracetamol, do not take paracetamol-containing preparations.
- If you know of any food or medicine sensitivity, inform your doctor.
- The preparation 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 preparations 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.

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

In particular inform your doctor or pharmacist if you are taking:

- Anticoagulants, particularly warfarin.
- Medicines against convulsions/epilepsy (carbamazepine, phenytoin, phenobarbital).
- Barbiturates.
- Rifampicin.
- Isoniazid, Zidovudine (for AIDS patients).
- NSAID preparations.
- 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 lactation:

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

Use in children:

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

3. HOW SHOULD YOU USE THE MEDICINE?

You should check with your doctor or pharmacist if you are unsure.

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. Contact your doctor if the fever persists for more than 3 days or if symptoms persist 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 insertion, chill it in the refrigerator for 30 minutes or place it under a stream cold water before removing the wrapper.
4. Wash your hands after inserting the suppository.

If you accidentally take a higher dose

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:

As 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 preparations 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).

- Signs of changes in the circulatory system, such as bleeding, bruising, inflammation developing more easily.

If any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by clicking the "report side effects due to medication" in the homepage of the Ministry of Health (www.health.gov.il) referring to an online form for reporting side effects, or by clicking the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

* Avoid poisoning! This medicine and any other must be kept out of the reach 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) that appears on the package. The expiry date refers to the last day of that month.

* Do not store at temperatures exceeding 25°C.

6. FURTHER INFORMATION

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

Hard fat (Witepsol H15)

What does the medicine look like and what are the contents of the package:

Oval milky-white suppositories.

Package contains 10 suppositories.

Drug registration number: 156-32-34427-00

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

Manufacturer:

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