

ABROLET SUPPOSITORIES

Composition:

Each suppository contains: Paracetamol 150 mg

Inactive ingredients: See section 6 "Further information"

Read the entire leaflet careful before using this medicine. This leaflet contains information about this medicine. If you have further questions, refer to the physician or pharmacist. This medicine is dispensed without prescription of doctor. This medicine is intended for administration to children between 3 years age and 6 years age for reduction of fever and relief pain.

Consult a doctor if fever persists for more than 3 days or if symptoms do not pass within 5 days despite use the treatment. You should give the medicine correctly. For further information consult your pharmacist.

1. what is this medicine intended for?

This medicine is intended to relieve pain and reduce fever.

Therapeutic Group: analgesic and antipyretic.

2. Before use this medicine:

Do not use this medicine if:

- If you have a known sensitivity (allergy) to paracetamol or to any of other ingredients of this medicine.

Special warnings regarding use of the medicine:

- If child have developed in the past skin side effects as a result of taking medicines containing paracetamol, do not take medicine containing paracetamol, so that severe skin effects will not recur.
- This medicine contains paracetamol which may cause liver damage when:
 - Given at a dosage higher than recommended, or for a prolonged period.
 - Consuming alcoholic beverages during the course of treatment.
 - Taking additional medicines which affect liver function.
- Do not use this medicine frequently, or for a long period, without consulting a doctor.
- Do not take additional antipyretics and analgesics or cold medicines without consulting a doctor or a pharmacist, to prevent paracetamol overdose/poisoning.
- Do not take others medicines containing paracetamol.
- Avoid taking a high dosages (within the recommended limit) of this medicine when fasting.
- If your child is sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
- This medicine contains soya oil. If you are allergic to soya or peanut, do not use this medicine.

Consult a doctor before commencing treatment if you are suffering or have suffered in the past from:

- Impaired function of the liver or liver disease
- Impaired function of the kidney
- Alcoholism
- hepatitis
- If you are pregnant or breastfeeding

If you are taking or if you have just finished treatment with another medicine including medicine over the counter, dietary supplement or vitamins, inform the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking a medicine from the following groups or if you have just finished treatment with the medicine:

- Medicines used to prevent blood clotting (Warfarin)
- Hepatic enzyme inducers (such as barbiturates, Rifampicin)
- Medicine to treat epilepsy (Phenytoin, carbamazepine)
- Non steroid anti-inflammatories medicines
- Domperidone or metoclopramide (to treat vomiting, nausea and other digestive problems)
- Chloramphenicol (Antibiotics)
- Probenecid (to treat the gout)
- Cholestyramine (used to reduce excess blood lipids)
- Do not take this medicine with other medicine containing paracetamol. You should check the composition of the medicine with the doctor or pharmacist

Use of this medicine and alcohol:

During the course of treatment with paracetamol, do not drink wine or alcoholic beverages due to increase risk of liver damage.

Pregnancy and breast-feeding:

If you are pregnant or breastfeeding, consult your doctor before the beginning of use this medicine.

Children use:

Parents should report to the attending doctor about any side effects and any medicine taking by your child. Do not take alcohol or other beverages containing alcohol to child during the treatment with this medicine.

3. How should you use the medicine?

If you are unsure how to use this medicine, you should consult your doctor or your pharmacist.

Recommended dosage unless otherwise prescribed by your doctor:

Under children under the 3 years: only according the recommendation of doctor.

In children between 3 to 4 years: 1 suppository, 4-5 time daily.

In children between 4 to 6 years: 1-2 suppositories, 4-5 time daily.

This medicine is not intended for children and babies under 2 years of age. For them, you have to use the liquid form.

Wait at least 4 hours before giving another dose.

Consult a doctor if fever persists for more than 3 days or if symptoms do not pass within 5 days despite the treatment.

Do not exceed the recommended dosage.

If the child accidentally received a double dose, consult your doctor immediately or contact the emergency room.

Do not swallow! This medicine is for rectal use only.

Do not cut / cross the suppository.

Direction of use:

Note: If the suppository is too soft for insertion put it in the refrigerator for 30 minutes or pour cold water on it **before opening the foil.**

1. How to insert the suppository: First, wash your hands thoroughly with water and soap.
2. Separate one suppository from the suppository strip. To remove the wrapper- separate the two tongue-shaped flaps of the flat part of wrapper.
3. Lie the child on the side and gently insert the suppository deep into the rectum with your finger.
4. Wash your hands thoroughly after the insertion.

If you have taken an overdose or if a child accidentally swallowed this medicine, immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without an explicit instruction from the doctor. Even if you feel well, prompt treatment is essential, **because the risk of developing severe liver damage.** Side effects can include nausea, vomiting, diarrhoea, loss of appetite, stomach pains, flatulence, excessive sweating, pain or tenderness in the upper abdomen and they may not reflect the severity of the liver damage.

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

4. Side Effects:

As with any medicine, use of **Abrolet suppositories** may cause side effects, such as redness or pain in the anal area in some of users. Do not be alarmed when reading this list if side effects. You may not suffer from any of them.

Serious side effects:

Stop the treatment and consult doctor immediately:

- If you are allergic reactions such as rash, itching, or rarely swelling of the face, lips, tongue, and throat that may cause difficulty breathing or swallowing,
- Paracetamol may cause, in the rare cases, serious skin diseases whose symptoms can include: redness, rash, blisters, widespread skin damage. Serious skin side effects may appear even if you had have no problems in the past when you had taken medicines containing paracetamol. If skin side effects appear, stop the treatment and consult a doctor immediately.
- If you sign of changes in the blood system such as bleeding, bruises, development of infections more easily.

If one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor immediately.

5. How to store this medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of reach of children and/ or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25° C.

6. Additional information:

In addition of active ingredient (substance) this medicine contains also:

Methylparaben, Propylparaben, Hard Fat, Soya Oil, BHT, BHA.

What does the medicine look like and what is the content of the package? White suppository in foil PE-ALUMINIUM. Each box contains 12 - 500 suppositories.

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

This leaflet was checked and approved it in November 2013

Registration number of this medicine in drug list of health ministry: 027 21 24032 00

For simplicity and easier to read, this leaflet is formulated male language, however, the medicines is intended for members of both sex.