

This medicine is sold without a doctor's prescription

ABROL TABLETS

This format of this leaflet was determined by the ministry of Health and its content was checked and approved in September 2013

Active Ingredient:

Each tablet contains: Paracetamol 500 mg

For Excipients agents: See section 6 "Additional information"

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about this medicine. If you have any additional questions, refer to the physician or pharmacist.

This medicine is dispensed without a doctor's prescription and it is intended for administration to adults and children over 12 years of age.

You should use and swallow the medicine correctly. For further information consult your pharmacist.

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

1. What is this medicine intended for?

This medicine is intended for the relief of pain and reduction of fever.

Group therapeutic: analgesic and antipyretic.

2. Before use this medicine:

Do not use this medicine if:

If you have a known sensitivity to paracetamol or to any of the medicine ingredients.

Special warnings related to the use of the medicine:

If you are developed on the past skin effects after you have taken medicine containing paracetamol, do not take medicine containing paracetamol in order to not develop again serious skin side effects

Medicine contains Paracetamol may cause liver damage in case of:

- Taking doses higher than the recommended dose, use for a long period of time,
- Drinking alcoholic beverage is while taking the medicine.
- Taking concomitantly other medicines having an impact on liver function.

Do not use this medicine frequently, or for a long period of time without consulting a doctor.

Do not take additional fever-reducing and pain-relieving medicines or medicines for common cold without consulting a doctor or a pharmacist, in order to prevent paracetamol overdose/toxicity.

Do not take others medicines containing paracetamol.

Avoid taking high dosages (on the border of what is recommended) while fasting.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

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

- Hepatic diseases, Impaired function of the liver,
- Impaired function of the kidney,
- Alcoholism,
- Hepatitis,
- If you are pregnant or breastfeeding.

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplement, vitamins. inform the doctor or the pharmacist. Specially, refer to the doctor or pharmacist if you take medicines of the following group or you finished the treatment with:

- 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 the fat in blood).
- In cases of use of other analgesics or antipyretics or anti-inflammatory drugs (in prolonged use).
- Alcohol.

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:

Do not drink wine or alcoholic beverages while under treatment with paracetamol because of the increased risk of hepatic damage.

Pregnancy and breast-feeding:

If you are pregnant or breastfeeding, consult your doctor before taking this medicine.

Important information regarding some the

ingredients of this medicine:

Each tablet of Abrol contains 0.36 mg of sodium.

Children use:

This medicine is intended for administration in adult and child over 12 years age, See section 3.

Parents should report to your doctor about any side effects and any medicine taking by your child.

3. How to 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:

Adults and children over the 12 years of age:

1-2 tablet, every 4-6 hours according the need.

Do not exceed 8 tablets per 24 hours.

Do not exceed the recommended dose.

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

Direction of use:

Do not chew! The tablets can be crushed if necessary.

Swallow the medicine with a small amount of water.

Do not drink wine or any other alcoholic beverages while using the medicine.

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

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.

4. Side Effects:

As with any medicines, use of Abrol tablet may cause side effects as dizziness in some of users. Do not be alarmed when reading this list of side effects. You may not suffer from any of them.

Serious side effects:

Stop the treatment and consult doctor immediately:

If you are severe allergic reactions such as rash, itching, or swelling of the face, lips, tongue, throat and / or limbs that may cause difficulty breathing or swallowing

Paracetamol can cause, in the rare cases, serious skin diseases whose symptoms can include: redness, rash, blisters, widespread damage to the surface of skin.

Serious skin side effects could appear also if you took in the past medicines containing paracetamol active substance without problem.

If serious side effects appear, stop the treatment and consult a doctor immediately.

If you see signs of changes in the blood system such as bleeding, bruising, development of infections more easily

If one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult your 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 in a dry and dark place, below 25°C.

6. Additional information:

In addition to the active ingredient the medicine also contains:

Talc, Magnesium Stearate, Starch, Aerosil, C.M.C Sodium, Ac-Di-Sol (croscarmellose sodium), Povidone

What does the medicine look like and what is the content of the package?

White tablet with REKAH engraved on one side, plain on the other.

License holder and manufacturer:

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St. Holon, Israel.

This leaflet was checked and approved by the Ministry of Health in: September 2013

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 028 47 21955 00

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