Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is to be supplied without physician's prescription

Rowatinex

Capsules

Active ingredients:

Pinene alfa	24.8 mg
Pinene beta	6.2 mg
Camphene	15 mg
Borneol	10 mg
Anethol	4 mg
Fenchone	4 mg
Cineole	3 mg

For the list of inactive ingredients – see section "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or to the pharmacist.

You should refer to the physician if the signs of the illness (symptoms) get worse or do not improve.

What is this medicine intended for?

Rowatinex is an adjuvant in infections of kidneys and urinary tract.

Rowatinex helps to dissolve, break down and eliminate stones from the kidneys and urinary tract. It relaxes the surrounding muscles, increases blood flow and decreases inflammation, and thus reduces pain and helps to remove the stones.

Rowatinex reduces the formation of stones by increasing the solubility of calcium salts, which are the main component of kidney and urinary tract stones.

Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to any of the active ingredients Camphene, Cineole, Fenchone, Borneol, Anethol, Pinene beta, Pinene alfa or to any of the other ingredients that this medicine contains (please see "Additional information")

Special warnings regarding the use of this medicine

Before the treatment with Rowatinex, tell your physician if:

- You are taking anticoagulants to thin the blood or medicines that are metabolized in the liver.

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, inform your physician or pharmacist. In particular if you are taking:

- Medicines to thin the blood (anticoagulants, such as Warfarin)
- Medicines that are metabolized in the liver.

Using the medicine and food

Rowatinex should be taken about half an hour before a meal.
During treatment with **Rowatinex** make sure to drink plenty.

Pregnancy and breastfeeding

There is no information on the use of **Rowatinex** during human pregnancy, and there is no evidence of a teratogenic effect in animals. However, some of the ingredients may pass through the placenta to the fetus, and therefore the

medicine should only be used during pregnancy after consultation with the physician and his assessment that the use of **Rowatinex** during pregnancy is essential.
If you are pregnant or breastfeeding, you should consult a physician or pharmacist before using this medicine.

Driving and using machines
The effect of **Rowatinex** on your ability to drive or operate machinery is unknown.

Important information about some of the medicine's ingredients
Rowatinex contains ingredients that could cause an allergic reaction: Sodium Ethyl Parahydroxybenzoate, Sodium Propyl Parahydroxybenzoate and Sunset Yellow FCF 85% (E110). Some of these ingredients may also cause a delayed allergic reaction.

How should you use the medicine?

You should check with the physician or the pharmacist if you are unsure.
The recommended dose is usually:

- **In adults:** 1-2 capsules 3 times daily
- **In Children aged 6 to 14 years:** 1 capsule twice daily

Do not exceed the recommended dose.

Consult the physician or the pharmacist regarding the duration of the treatment.
Swallow the capsule whole. Do not bite or chew the capsule.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the medicine as soon as you remember and continue with the recommended dose.
Persist with the treatment as recommended by the physician.

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

If you have any further questions regarding the use of this medicine, consult the physician or the pharmacist.

Side effects

As with any medicine, the use of **Rowatinex** may cause side effects in some users.

If any side effect which wasn't mentioned in this leaflet appears, consult with the physician.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Do not store above 25°C.

Additional information

- In addition to the active ingredients, the medicine also contains:
  Virgin Olive Oil, Capsule Shell: Gelatin, Glycerol 85%, Sodium Ethyl Parahydroxybenzoate, Sodium Propyl Parahydroxybenzoate, Sunset Yellow FCF 85% (E110), Quinoline Yellow WS 70% (E104).
- What does the medicine look like and what are the contents of the package:

Rowatinex is supplied in a box of blister packs containing spherical, yellow capsules made of gastro-resistant soft gelatine. The capsules contain a pale yellow to greenish solution with a strong aromatic odour.

Each pack contains 50 or 20 capsules. Not all pack sizes may be marketed.

- Marketing Authorization Holder and his address: MegaPharm Ltd., P.O.B. 519, Hod Hasharon 4510501.
- Manufacturer and his address: Rowa Pharmaceuticals Ltd., Newtown, Bantry, Cork county, Ireland.
- This leaflet was checked and approved by the Ministry of Health in September 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 107-67-20546.