PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed without a physician's prescription

Rowatinex Capsules

Active ingredients:

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

For a list of inactive and allergenic ingredients in the preparation, see chapter 2 Section "Important information about some of the medicine's ingredients" and chapter 6 "Additional information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, consult your physician or pharmacist.

Take the medicine in accordance with the instructions in chapter 3 "How should you use the medicine?". Consult with a pharmacist if you require more information. Consult with a physician if the symptoms of the illness get worse or do not improve after 14 days. The duration of treatment may vary depending on the size of the stones and the physician's diagnosis.

1. What is this medicine intended for?

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

Rowatinex helps to dissolve, break down and remove kidney and urinary tract stones. **Rowatinex** relaxes muscles in the area, increases blood flow and reduces inflammation, thus reducing pain and helping 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.

2. Before using the medicine

Do not use this medicine if:

You are sensitive (allergic) to any of the active ingredients, Camphene, Cineole, Fenchone, Borneol, Anethole, Pinene beta, Pinene alfa, or to any of the additional ingredients contained in the medicine (please see chapter 6 "Additional information").

Special warnings regarding the use of the medicine: Before treatment with Rowatinex, tell your physician if:

• You are taking Blood-thinning medications or medicines that are broken down in the liver.

Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medicines or nutritional supplements, tell your physician or pharmacist. Particularly if you are taking:

- Blood-thinning medications (anti-coagulants e.g., warfarin).
- Medicines that are broken down in the liver.

Use of the medicine and food

Take **Rowatinex** about half an hour before a meal.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, consult with your physician or pharmacist before using the medicine.

Driving and using machines

No effect is expected on your ability to drive or use machines.

Important information about some of the medicine's ingredients

Rowatinex contains ingredients that may cause allergic reaction:

Sodium Ethyl Parahydroxybenzoate (E215)

Sodium Propyl Parahydroxybenzoate (E217)

Sunset Yellow FCF 85% (E110)

A delayed allergic reaction may also occur.

3. How should you use the medicine?

You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen with this medicine.

The usual dosage is generally:

- Adults: 1 to 2 capsules, 3 times daily.
- Children aged 6-14 years: 1 capsule , twice daily.

Do not exceed the recommended dose.

Ask your physician or pharmacist for advice as to how long you should use the medicine.

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, immediately consult with a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the required time, do not take a double dose. Take it as soon as you remember, and continue with the recommended dose.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take a medicine. Wear glasses if you need them.

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

4. Side effects

As with any medicine, the use of **Rowatinex** may cause side effects in some users. If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking the link "Report adverse effects associated with medications" on the homepage of the Ministry of Health website (www.health.gov.il), which directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

5. How should the medicine be stored?

• Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.

• Do not use this medicine after the expiry date (exp. date) which appears on the package exterior. The expiry date refers to the last day of that month.

Storage conditions:

Store at a temperature below 25°C.

6. Additional information

• In addition to the active ingredients, the medicine also contains:

Virgin Olive Oil,

Capsule Shell: Gelatin, Glycerol 85%, Sodium Ethyl Parahydroxybenzoate (E215), Sodium Propyl Parahydroxybenzoate (E217), Quinoline Yellow WS- 70% (E104), Sunset Yellow FCF 85% (E110).

• What the medicine looks like and what the package contains:

Rowatinex is supplied in a pack, inside which are blister trays containing yellow ballshaped (spherical) capsules made of soft gastro-resistant gelatine. The capsules contain a pale yellow to greenish solution with a strong aromatic odour.

Each pack contains 50 or 20 capsules.

Not all package sizes may be marketed.

- Registration holder and address: Megapharm Ltd., 15 Hatidhar St., Ra'anana, Israel.
- Manufacturer and address: Rowa Pharmaceuticals Ltd., Bantry, Ireland.
- This leaflet was revised in April 2023 in accordance with the guidelines of the Ministry of Health.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 107-67-20546.

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