

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

This medicine is dispensed without a physician's prescription

Rowachol Capsules

Active ingredients:

Menthol	32 mg
Menthone	6 mg
β -Pinene	3.4 mg
Borneol	5 mg
Camphene	5 mg
Cineole	2 mg
α-Pinene	13.6 mg

For a list of the inactive and allergenic ingredients in the preparation, see Chapter 2 under the heading "Important information about some of this 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 to use this 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?

Rowachol is used as an adjuvant in the treatment of gallbladder stones and liver diseases.

Rowachol acts to dissolve, disintegrate and remove gallstones by increasing bile secretion. **Rowachol** also inhibits the formation of substances that contribute to deposit build-up and stone formation. **Rowachol** relaxes the bile ducts, thus reducing pain and helping to remove the stones.

2. Before using the medicine

Do not use this medicine if:

You are sensitive (allergic) to α-pinene, β-pinene, borneol, menthol, menthone, camphene, cineole, or any of the additional ingredients in this medicine (please see Chapter 6, "Additional information").

Special warnings regarding the use of this medicine: Do not take Rowachol unless your physician has confirmed a diagnosis of gallstones, especially in the case of children.

Before treatment with Rowachol, tell your physician if:

- You are taking blood-thinning medicines 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 medicines (anticoagulants, e.g. warfarin).
- Medicines that are broken down in the liver.

Use of the medicine and food

Take **Rowachol** before meals.

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

Rowachol contains ingredients that may cause an allergic reaction:

Sodium ethyl parahydroxybenzoate (E215)

Sodium propyl parahydroxybenzoate (E217)

A delayed allergic reaction may also occur.

3. How to use this medicine?

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

The standard dosage is usually:

- **Adults:** 1-2 capsules, 3 times daily, before meals.
- **Children aged 6-14 years old:** 1 capsule, twice daily, before meals.

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 every time 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 **Rowachol** 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.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking the link “Report adverse effects associated with medicines” 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. 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), sodium copper chlorophyllin (E141 100% water soluble).

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

Rowachol is supplied in a box, inside which are blister trays containing green ball-shaped (spherical) capsules made of soft gastro-resistant gelatin. The capsules contain a greenish-yellow solution with a strong aromatic odour.

Each box contains 20, 50 or 100 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., Newtown, Ireland.
- This leaflet was revised in May 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: 107-68-20688.

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