

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is to be supplied without physician's prescription

## **Rowachol®**

### **Capsules**

#### **Active ingredients:**

L-Menthol 32 mg  
Menthone 6 mg  
Pinene beta 3.4 mg  
Pinene alfa 13.6 mg  
Borneol 5 mg  
Camphene 5 mg  
Cineole 2 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.

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

### **What is this medicine intended for?**

**Rowachol** is used as a supplement for the treatment of gallstones and liver diseases.

**Rowachol** acts by dissolving, breaking up and expelling gallstones by increasing the secretion of bile. In addition, **Rowachol** inhibits the formation of substances contributing to the generation of sediments and formation of stones. **Rowachol** relaxes the bile ducts, thus reducing pain and facilitating expulsion of gallstones.

### **Before using this medicine**

#### **Do not use this medicine if:**

You are sensitive (allergic) to any of the active ingredients L-Menthol, Menthone, Pinene alfa, Pinene beta, Borneol, Camphene, Cineole 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 Rowachol, tell your physician if:**

- you are taking anticoagulants to thin the blood or medicines that are broken down by the liver.

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

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

#### **Using the medicine and food**

**Rowachol** should be taken before meals.

A low cholesterol diet is recommended.

#### **Pregnancy and breastfeeding**

There is no information on the use of **Rowachol** during human pregnancy, and there is no evidence of a teratogenic effect in animals. 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 **Rowachol** during pregnancy is essential.

If you are pregnant or breastfeeding, you should consult a physician or a pharmacist before using this medicine.

#### **Driving and using machines**

The effect of **Rowachol** on your ability to drive or operate machinery is unknown.

### **Important information about some of the medicine's ingredients**

**Rowachol** contains ingredients that could cause an allergic reaction: Sodium Ethyl Parahydroxybenzoate, Sodium Propyl Parahydroxybenzoate. 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, before meals.
- **In Children aged 6 to 14 years:** 1 capsule, twice daily, before meals.

#### **Do not exceed the recommended dose.**

Consult the physician or the pharmacist regarding the duration of the use of this 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,** 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 **Rowachol** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

In rare cases, eructation and a peppermint taste in the mouth may occur after meals. These effects can be reduced by taking the medicine on an empty stomach approximately 30 minutes before meals.

A few patients reported occurrence of mouth pain and ulcers in the mouth. This effect is reversible and resolves rapidly upon discontinuation of the medicine.

If any side effect appears, if any side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

#### **Reporting side effects:**

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](http://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, Sodium Copper Chlorophyllin (E141).
- What does the medicine look like and what are the contents of the package:  
**Rowachol** is supplied in a box of blister packs containing round green capsules, made of gastro-resistant soft gelatine. The capsules contain a greenish-yellow solution with a strong aromatic odour.  
Each pack contains 20, 50 or 100 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 July 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 107-68-20688.