

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowachol Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

α -Pinene 13.6 mg, β -Pinene 3.4 mg, L-Menthol 32.0 mg, Menthone 6.0 mg, Borneol 5.0 mg, Camphene 5.0 mg, Cineole 2.0 mg.

Each capsule also contains Sodium Ethyl Parahydroxybenzoate and Sodium Propyl Parahydroxybenzoate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gastro-resistant Capsules, soft

Spherical, green, soft gelatin, gastro-resistant capsules containing a greenish yellow oral solution with a strong aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

An adjuvant in the treatment of gall-bladder stones and liver diseases.

4.2 Posology and method of administration

Route of Administration: Oral.

Recommended Dosage Schedule:

Adults: The usual dosage is 1 to 2 capsules three times daily before meals.

Children aged 6 to 14 years: The usual dosage is 1 capsule twice daily before meals.

4.3 Contraindications

Known hypersensitivity to any of the active ingredients or to any of the inactive ingredients in the formulation.

4.4 Special warnings and precautions for use

The product should only be used with caution in patients on anti-coagulants or drugs dependent on the liver for metabolism and excretion.

The following ingredients of Rowachol capsules may cause allergic reactions: Sodium Ethyl Parahydroxybenzoate (E215), Sodium Propyl Parahydroxybenzoate (E217) (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Rowachol Capsules should only be used with caution in patients on anti-coagulants or drugs dependent on the liver for metabolism and excretion.

4.6 Fertility, pregnancy and lactation

There is no information on experience of use during human pregnancy. There is no evidence of a teratogenic effect in animals. However, some at least of the ingredients can cross the placenta. The product should therefore only be used during pregnancy or lactation if considered essential by the physician.

4.7 Effects on ability to drive and use machines

There is no evidence of impairment of these functions in patients taking Rowachol Capsules.

4.8 Undesirable effects

In rare cases, symptoms of belching and mint taste in the mouth have been reported, after meals. These symptoms can be reduced by taking medication on an empty stomach 30 minutes before a meal.

A small number of patients reported appearance of pain and ulcers in the mouth. This phenomenon is reversible and disappeared soon after stopping treatment.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

(<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>).

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The several ingredients are well absorbed, metabolised in the liver and excreted in bile and urine.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Virgin Olive Oil

Capsule Shell: Gelatine Glycerol 85%, Sodium Ethyl Parahydroxybenzoate, Sodium Propyl Parahydroxybenzoate, Sodium Copper Chlorophyllin (100% water soluble).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed.

6.5 Nature and contents of container

Rowachol Capsules are packed in white, polypropylene tablet containers with polyethylene matt white circular caps. The caps have 'tear-strips' fully attached all around and a 'pull-off lip' above the 'tear-strip'.

Rowachol Capsules are available in tablet containers of 50 and 100 capsules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. LICENSE HOLDER

Megapharm Ltd., P.O.Box 519 Hod Hasharon, 4510501

8. MANUFACTURER

Rowa Pharmaceut. LTD.

Newtown, Bantry Co. Cork, Ireland

9 ISRAEL LICENSE NUMBER

107-68-20688

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