Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowachol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
α-Pinene 13.6 mg, ß-Pinene 3.4 mg, Menthol 32.0 mg, Menthone 6.0 mg, Borneol 5.0 mg, Camphene 5.0 mg, Cineole 2.0 mg.

Excipient(s) with known effect
Each capsule also contains Sodium Ethyl Parahydroxybenzoate (E215) and Sodium Propyl Parahydroxybenzoate (E217).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gastro-resistant Capsules,
Soft spherical, green, soft gelatine, gastro-resistant capsules containing a greenish yellow oral solution with a strong aromatic odor.

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

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

A definite diagnosis of radiolucent gallstones must be made before taking this product to rule out other possible conditions. The product should only be used with caution in patients on anti-coagulants or drugs dependent on the liver for metabolism and excretion.
Conservative medical management of cholelithiasis should be initiated with the awareness that stones can give rise to serious clinical complications, especially if the stones obstruct the common bile duct such as obstructive jaundice, ascending cholangitis, sepsis, acute pancreatitis. The physician should be aware of the necessity of being properly informed [particularly in the case of elderly patients] so that appropriate measures can be taken.

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

A slight taste of peppermint may occur initially.-No case of side effects has been reported.

Reporting of suspected adverse reactions
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 https://sideeffects.health.gov.il.

4.9 Overdose

No cases of overdose have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Rowachol is a gallstone dissolving/disintegration agent. Rowachol dissolves cholesterol gallstones and desaturates the bile in relation to cholesterol. The product is a potent choleretic increasing biliary secretions and reducing biliary statis, it has antispasmodic activity reducing spasm pain. Its HMGCoA reductase inhibitory activity reduces endogenous cholesterol production, lowering saturation index of bile thus assisting the dissolution of cholesterol gallstones and preventing precipitation of further stones.

5.2 Pharmacokinetic properties

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

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 (E215)
Sodium Propyl Parahydroxybenzoate (E217)
Sodium Copper Chlorophyllin (100% water soluble)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

6.4 Special precautions for storage

store below 25°C.

6.5 Nature and contents of container

Rowachol Capsules are packed in PVC/PCDC/ALUMIIUM BLISTERS.

Rowachol Capsules are available in boxes of 20, 50 and 100 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7.0 LICENSE HOLDER

Megapharm Ltd., 15 Ha'Tidhar street, Ra'anana, Israel.

8.0 MANUFACTURER

Rowa Pharmaceut. LTD.,Ireland

Newtown, Bantry Co. Cork, Ireland

9.0 ISRAEL LICENSE NUMBER

107-68-20688-01

10. DATE OF REVISION OF THE TEXT

Revised in May 2023 according to MOH guidelines.