SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rowachol Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains the following:

Pinene [$^{\alpha}$ + $^{\beta}$]	17.0 mg
Camphene	5.0 mg
Cineol BPC 1973	2.0 mg
Menthone	6.0 mg
Menthol BP	32.0 mg
Borneol	5.0 mg

3. PHARMACEUTICAL FORM

Green spherical, soft, enteric-coated gelatin capsules containing a pale yellow or tinted greenish-yellow oil.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Adjunct therapy for the dispersal [by dissolution and/or expulsion] of stones in the common bile duct. To be used in combination with chenodeoxycholic acid.

It has been demonstrated that if ROWACHOL is combined with either low or medium dose chenodeoxycholic acid, the gallstone dissolution rate is greater than if the same dose of chenodeoxycholic acid is used alone. Combined therapy enables a reduced dose of chenodeoxycholic acid to be used and there is therefore a lower incidence of side effects.

ROWACHOL increases biliary secretion, relieves spasm of the bile ducts, enhances metabolic liver function, reducing biliary stasis. By inhibiting HMGCoA reductase endogenous cholesterol production is reduced, maintaining the bile above saturation level, assisting dissolution of gallstones and preventing precipitation of further stones.

4.2 Posology and Method of Administration

For oral administration only.

Adult Dose:

1-2 capsules three times daily, taken before meals. A dose of one capsule three times daily is recommended at the start of treatment.

Children:

There Is no recommended dose for children.

4.3 Contra-Indications

None known.

4.4 Special Warnings and Special Precautions for Use

Conservative medical treatment for stones in the common bile duct should be initiated with the awareness that duct stones can give rise to clinical complications such as obstructive jaundice, ascending cholangitis, pancreatitis, etc. and 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.

Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be used in patients receiving oral anticoagulants or other agents metabolised by the liver where the dose is critical.
Reduced cholesterol intake in diet is advisable.

4.6 Pregnancy and lactation

Although no teratogenic effects have been reported, ROWACHOL should not be given in the first trimester of pregnancy. Although no evidence is available, ROWACHOL should not be given to lactating females.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects are uncommon and minor. A small number of patients have noted eructation and a peppermint taste after meals. This can be reduced or avoided by administration of drug on an empty stomach thirty minutes before meals.

An insignificant number of patients noted soreness of mouth and buccal ulceration - an effect which can be rapidly reverted by discontinuation of the drug.

4.9 Overdose

If medication has been recently ingested, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary. Monitoring of cardiac, respiratory, renal and hepatic functions are advised.

Toxicology experiments in animals suggest that massive doses of essential oils may result in CNS depression leading to stupor and respiratory failure or stimulation leading to excitement and convulsions.

Gastric irritation may occur leading to nausea, vomiting and diarrhoea.

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 secretion and reducing biliary stasis, 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

Bioavailability studies demonstrate rapid oral absorption, e.g. Menthol is rapidly absorbed, metabolised in the liver and excreted in the urine and bile as glucuronides. Absorption half life T2-β 0.373 ± 0.081 hours; peak plasma concentration – conjugates 2.467 ± 0.663 mg -L; elimination half-life (t½β) - 0.861 ± 0.148 [mean hr ± SEM].

5.3 Pre-clinical Safety Data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Constituent Olive oil BP	33 mg per 100 mg of product
Capsule Shell	mg per capsule shell
Gelatine DAB, Ph Eur	52.2
Glycerine DAB, Ph Eur	22.4
Ethyl-p-Hydroxybenzoate Sodium Salt Ph. France	0.225
Propyl-4-Hydroxybenzoate Sodium Salt BP	0.11
Sodium Copper Chlorophyllin E141	0.055

6.2 Incompatibilities

None known.

6.3 Shelf life

(i) Unopened Container: 5 years
(ii) Opened Container: 5 years

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

Securitainer tube plus jayfilla plus cap containing 50 or 500 capsules.

6.6 Instruction for Use, Handling and Disposal

Replace cap after use.

7 MARKETING AUTHORISATION HOLDER

ROWA PHARMACEUTICALS LIMITED,
Newtown,
Bantry,
Co. Cork,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

PL 0007/0006

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

[a] 19 April 1983 - PL 0007/0002
[b] 3 February 1989 - PL 0007/0002 [Renewal]
[c] 2 September 1994- PL 0007/0006

10. DATE OF (PARTIAL) REVISION OF THE TEXT

December 2001.