



Rowachol[®]

INFORMATION LEAFLET

Presentation

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

Composition

Capsules: Each enteric-coated capsule contains -

Pinene ($\alpha+\beta$) 17 mg, Camphene 5 mg, Cineol 2 mg, Menthone 6 mg, Menthol 32 mg, Borneol 5 mg and Olive Oil 33 mg.

Pharmacodynamics

Rowachol[®] increases biliary secretion, relieves spasm of the bile ducts, enhances metabolic liver function by reducing biliary stasis. By inhibiting HMGCoA reductase, endogenous cholesterol production is reduced, maintaining the bile above saturation level, assisting the dissolution of gallstones and preventing precipitation of further stones. The choleresis produced by **Rowachol[®]** increases insulin production, assisting in the control of diabetic states.

Pharmacokinetics

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

Studies were performed on some of the terpenes contained in **Rowachol[®]**. There are a few pharmacokinetic studies on menthol, one of the major constituents of **Rowachol[®]**.

A major route of metabolism of terpenes e.g. menthol or borneol is via their glucuronides.

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 T_{2-β} 0.373 + 0.081 hours; peak plasma concentration - conjugates 2.467 + 0.663 mg · L⁻¹; elimination half-life T_{2-β} 0.861 + 0.148 [mean hr + SEM].

In comparative study on bioavailability of Rowachol in capsule and liquid form in volunteers, menthol was used as marker component. Blood samples were assayed for menthol by GLC after enzymatic treatment to liberate menthol by glucuronide - the main metabolite. Rowachol was subject to rapid first pass metabolism, the conjugate appearing in blood after about 15 minutes.

Glucuronic acid can solubilise calcium salts, an ability enhanced if it is conjugated. Menthyl glucuronide provide an effective solution for calcium salts e.g. addition of 2.5 ml of an 0.8 M ammonium menthyl glucuronide solution will dissolve the precipitate of calcium carbonate formed by mixing 0.25 ml each of 0.1 M CaCl₂ and 0.1 M Na₂CO₃.

Rowachol can bring about the dissolution of cholesterol gallstones in the gallbladder and common bile duct. In combination with low or medium dose chenodeoxycholic acid 7.0 - 10.5 ml/kg daily can bring about dissolution of cholesterol stones in the gallbladder.

Indications

For the treatment of hepatobiliary disorders including cholelithiasis, cholecystitis, bile duct dyskinesia, inflammatory hepatic conditions.

Dosage and Administration

Route of Administration: Oral.

Recommended Dosage:

Adults: Unless otherwise directed by the physician, the usual dose is 1 - 2 capsules 3 times daily before meals.

Children 6-14 years: The usual dose is 1 capsule twice daily before meals.

Contra-indications, Warnings, etc.**Contra-indications**

There are no known contra-indications to the use of **Rowachol**[®].

Warnings and Precautions

Care should be exercised in the dosage of patients receiving anti-coagulants or drugs dependant on the liver for metabolism and excretion.

Reducing fat intake in the diet is advisable.

Pregnancy and Lactation

Although no teratogenic effects have been reported, it is advisable that pregnant women should not take **Rowachol**[®] during the first trimester of pregnancy.

Side Effects

No untoward side effects have been reported. A slight taste of peppermint may occur initially.

Symptoms and Treatment of Overdose

If recently ingested the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary.

Storage Conditions

Store below 30°C.

Keep all medicines out of the reach of children.

Shelf life:

5 years.

Package Quantities

Container of 50 capsules.

Blister packs of 50 and 100 capsules.

Date of Revision

This leaflet was last revised in April 2024.

Artwork Checklist

Job Description Rowachol PIL RCF 16237	Version Number 01	Size 140 x 210	Inks ■ Black	ACCF 25277
Market Malaysia	Proof Date 25/09/2024	Cutter Ref. N/A	Colour □ None □ Black	