Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowachol Oral Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of oral drop solution contains:
α -Pinene 13.6 g, ß-Pinene 3.4 g Menthol 32.0 g, Menthone 6.0 g, Borneol 5.0 g, Camphene 5.0 g, Cineole 2.0g.
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Drops, Solution

Pale yellow to greenish-yellow oral drop solution with a strong aromatic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management and dissolution of radiolucent gallstones in the functioning gall bladder **where a definite diagnosis has been made by a doctor especially in the case of children.**

4.2 Posology and method of administration

Posology

Method of Administration: Oral.

Adults: 3 to 5 oral drops three times daily before meals.

Paediatric Population:

Children 0-6 years: No data are available

Children aged 6 to 14 years: 1 to 2 oral drops three times daily before meals.

Adolescents aged 14-18 years: 3 to 5 oral drops three times 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

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.

4.5 Interaction with other medicinal products and other forms of interaction

Rowachol Oral Drops 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 oral drops.

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Rowachol is a gallstone dissoving/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, metabolised 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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25ºC. Keep the bottle tightly closed.

6.5 Nature and contents of container

Rowachol Oral Drops is packed in amber, round glass bottles with LDPE dropper and aluminium cap.
Rowachol Oral Drops is available in bottles of 10 ml.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Ltd
Newtown
Bantry
Co Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/008/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983

Date of last renewal: 1st April 2008

10 DATE OF REVISION OF THE TEXT

March 2018