

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowachol Gastro-resistant Capsules, Soft

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

α -Pinene 13.6 mg, β -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 the 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 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: 1 to 2 capsules three times daily before meals.

Paediatric Population:

Children aged 0 to 6 years: No data are available.

Children aged 6 to 14 years: 1 capsule twice daily before meals.

Adolescents aged 14 to 18 years: 1 to 2 capsules 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.

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 interactions

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRC 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 dissolving/disintegration agent. Rowachol dissolves cholesterol gallstones and desaturates the bile in relation to cholesterol. The product is a potent choleric increasing biliary secretions 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

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

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

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 500 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Limited

Newtown

Bantry

Co. Cork

Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/008/001

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

17 February 2020

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