Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowatinex Oral Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g of oral drops solution contains:
α-Pinene 24.8 g, β-Pinene 6.2 g, Camphene 15.0 g, Borneol 10.0 g, Anethol 4.0 g, Fenchone 4.0 g, Cineole 3.0 g.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Drops, solution

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

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of urolithiasis **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 4 to 5 times daily before meals or in the presence of colic 20 to 30 oral drops 4 to 5 times daily.

Paediatric Population

Children aged 0 to 6 years: No data are available

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

Adolescents aged 14 to 18 years: 3 to 5 oral drops 4 to 5 times daily before meals or in the presence of colic 20 to 30 oral drops 4 to 5 times daily.

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 urolithiasis and nephrolithiasis must be made before taking this product to rule out other possible conditions.

Conservative medical management of uro- and nephrolithiasis should be initiated with the awareness that stones can give rise to serious clinical complications such as obstruction of the urinary system, sepsis. The physician should be aware of the necessity of being properly informed so that appropriate measures can be taken.

The product should only be used with caution in patients on anti-coagulants or drugs dependent on the liver for metabolism and excretion.

4.5 Interaction with other medicinal products and other forms of interaction

Rowatinex 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 Rowatinex Oral Drops.

4.8 Undesirable effects

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

Rowatinex promotes the disintegration and elimination of renal and urinary tract stones. Terpenes such as borneol are metabolised and excreted in the urine mainly in the form of glucuronides, which increase the solubility of calcium salts (the main components of renal and urinary stones). The inhibitory effect of Rowatinex on the formation of renal and urinary calculi has been established in a number of animal studies.
Rowatinex has spasmolytic action promoting the passage of stones in the tracts and reducing the pain of renal and ureteric colic. Rowatinex has a hyperaemic effect and reduces inflammatory effects.

Rowatinex has anti-bacterial activity against a range of gram-positive and gram-negative organisms.

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 25°C. Keep the bottle tightly closed.

6.5 Nature and contents of container

Rowatinex Oral Drops is packed in amber, round glass bottles with LDPE dropper and aluminium cap.
Rowatinex 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

PA0074/009/002

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