

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Rowatinex Gastro-resistant Capsules, Soft

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

$\alpha$ -Pinene 24.8 mg,  $\beta$ -Pinene 6.2 mg, Camphene 15.0 mg, Borneol 10.0 mg, Anethol 4.0 mg, Fenchone 4.0 mg, Cineole 3.0 mg.

Excipient(s) with known effect

Each capsule also contains Sodium Ethyl Parahydroxybenzoate (E215), Sodium Propyl Parahydroxybenzoate (E217) and Sunset Yellow FCF 85% (E110).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gastro-resistant Capsules, soft

Yellow, spherical, soft gelatine gastro-resistant capsules containing a pale yellow to greenish-yellow oral 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: 1 capsule 4 to 5 times daily before meals.

*Paediatric Population:*

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

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

Adolescents aged 14 to 18 years: 1 capsule 4 to 5 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 urolithiasis and nephrolithiasis 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 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.

Rowatinex capsules contain sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

Rowatinex also contains sunset yellow FCF 85% (E110) which may cause allergic reactions.

## 4.5 Interaction with other medicinal products and other forms of interaction

Rowatinex 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 Rowatinex Capsules.

## 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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

### Capsule shell

Gelatine

Glycerol 85%

Sodium Ethyl Parahydroxybenzoate (E215)

Sodium Propyl Parahydroxybenzoate (E217)

Sunset Yellow FCF 85% (E110)

Quinoline Yellow 70% (E104)

## **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**

Rowatinex 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'.

Rowatinex 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 Ltd  
Newtown  
Bantry  
Co Cork  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA0074/009/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> April 1983

Date of last renewal: 1<sup>st</sup> April 2008

**10 DATE OF REVISION OF THE TEXT**

March 2018