

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

ROWATINEX Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains the following:

Pinene [α + β]	31.0mg
Camphene	15.0 mg
Cineol BPC	3.0 mg
Fenchone	4.0 mg
Borneol	10.0 mg
Anethol USP	4.0 mg

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Urolithiasis, nephrolithiasis and mild urinary tract infections. ROWATINEX promotes the disintegration of stones, and by its spasmolytic action promotes the spontaneous passage of stones in the renal and urinary tracts. ROWATINEX gives symptomatic relief of mild to moderate renal and urinary colic associated with the presence of stones in the renal and urinary tracts. ROWATINEX is also indicated for the relief of frequency and urgency associated with mild urinary tract infections.

4.2 Posology and method of administration

Route of Administration: Oral.

Adults: One capsule 3 or 4 times daily before meals.

No dose recommendation for children.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

ROWATINEX is not suitable for use in patients with severe colic, anuria or severe infection of the urinary tract.

Keep out of the reach of children.

4.5 Interactions with other medicinal products and other forms of interaction

Should not be used in patients receiving oral anti-coagulants or other drugs metabolised by the liver where dose is critical.

4.6 Pregnancy and lactation

Although no teratogenic effects have been reported, ROWATINEX should not be given in the first trimester of pregnancy. Although no evidence is available, ROWATINEX should not be given to lactating females.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

An Insignificant number of patients reported slight and transient gastric disturbance. Vomiting has been rarely reported. In two cases there was drug intolerance [cause unknown] - side effects were uncommon and minor.

4.9 Overdose

If medication has been recently ingested, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary. Monitoring of cardiac, respiratory, renal and hepatic functions are advised.

Rats given lethal doses of ROWATINEX orally develop a condition similar to narcosis, losing their corrective power and die in deep somnolence.

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 colics. 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 terpenes present in ROWATINEX are lipid soluble and rapidly absorbed.

Terpenes such as Borneol are substantially metabolised in man and animals to their glucuronides which are eliminated in the urine.

5.3 Preclinical safety data

ROWATINEX is a therapeutic agent which has been established for a number of years and is currently available in many countries. A substantial number of clinical trials and many years of patient usage have established that ROWATINEX is an effective and safe agent for the treatment of many disorders associated with urolithiasis and nephrolithiasis and for the relief of symptoms associated with these disorders. Based on well known terpenes used

in therapy for many years, the patient tolerance and acceptability of the product is high and side effects recorded in clinical trials minimal.

The physiological and pharmacological actions of the product combine to create an environment where the dissolution and/or disintegration of stones and their elimination is facilitated and the associated symptomatic relief achieved.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

mg/capsule

Olive Oil BP 33.00 mg

Capsule Shell:

Gelatin Ph. Eur.	52.065 mg
Glycerol 85% Ph. Eur.	22.410 mg
Sodium Ethyl Hydroxybenzoate Ph. France	0.225 mg
Sodium Propyl Hydroxybenzoate Ph.Eur.	0.110mg
Quinoline Yellow, WS 70% E1 04	0.225 mg
Sunset Yellow FCF 85% E110	0.006mg

6.2 Incompatibilities

None known.

6.3 Shelf life

(i) Unopened Container:	5 years
(ii) Opened Container:	5 years
(iii) After reconstitution:	Not applicable

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Securitainer pack of 50 and 500 capsules.

6.6 Instructions for use/handling

Replace cap after use.

7. MARKETING AUTHORISATION HOLDER

ROWA PHARMACEUTICALS LTD
Newtown
Bantry
Co. Cork
Ireland

8. MARKETING AUTHORISATION NUMBER

PL 00007/0003R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[a] 20 January 1989 - PL 00007/0003R
[b] 27 April 1994 - PL 00007/0003R [Renewal]
[c] 15 April 1999 - PL 00007/0003R [Renewal]
[d] 29 June 2004 - PL 00007/0003R [Renewal]

10. DATE OF (PARTIAL) REVISION OF TEXT

29/06/2004