

ROWATINEX® Gastro-Resistant Capsules
ROWATINEX® Oral Drops Solution

ROWAtinex®

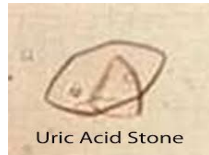
ROWA®
Pharmaceuticals Limited

ROWA PHARMACEUTICALS LTD
ROWA WAGNER GmbH & Co. KG

GENERAL INFORMATION

General Information

Kidney Stones



1

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

Urinary Stones:

The condition of having kidney stones is termed **nephrolithiasis**. Having stones at any location in the urinary tract is referred to as **urolithiasis** and the term **ureterolithiasis** is used to refer to stones located in the ureters.

A kidney stone is a hard, crystalline mineral material formed within the kidney or urinary tract. These crystals can develop into stones over weeks or months. Other substances such as certain medicines can also form stones.

Chronic Diseases:

Diabetes and high blood pressure (hypertension) are also associated with an increased risk of developing kidney stones.

Lifestyle and Diet:

The incidence of urolithiasis is increasing because of changes in dietary habits and general lifestyle*.

Urinary pH and Stone Formation: **

An alkaline pH favours the crystallisation of calcium and phosphate containing stones, whereas an acidic urine pH promotes uric acid or cysteine stones.

Low urinary pH and defective renal ammonia genesis was linked to insulin resistance.

Low urinary pH in patients with uric acid nephrolithiasis is due to defective ammonium excretion and increased acid production, which may both be linked to renal insulin resistance. The reversal of insulin resistance may ameliorate these defects and increase urinary pH.*** (ROWATINEX® had no influence on the pH value in patients that participated in the clinical trial in Hungary****)

*	Menditto et al; Metaphylaxis of urolithiasis 2009 PMID 19499756	***	Khashayar Sakhaee; Urinary pH as a risk factor for stone type. Dept of Internal medicine University of Texas Southwestern Medical Center Dallas Texas. CP900/Renal Stone Disease 1st Annual International Urolithiasis Research Symposium
**	Wagner CA et al; Urinary pH stone formation 2010 PMID 21170875	****	Romics I; Trial to evaluate the efficacy of ROWATINEX® in elimination of fragments of calculi generated by ESWL. A placebo controlled multi-centre study. Feb 2009. Dept. of Urology, Semmelweis, Ulloi ut 89-95, Budapest, Hungary. ROWATINEX® 2002/HU; S59-NEP-0

2

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

Stone Composition:

Type	Incidence	Crystal Shape	Risk Factors
Calcium Oxalate/ Phosphate	75-80%	Envelope	<ul style="list-style-type: none"> • Hypercalciuria • Hyperuricosuria • Hyperoxaluria • Hypocitraturia • Low Urine Volume
Calcium Phosphate (Brushite)	5%	Amorphous	<ul style="list-style-type: none"> • Hypercalciuria • Hyperphosphaturia • Raised Urinary pH
Uric Acid	5-10%	Diamond or Barrel	<ul style="list-style-type: none"> • Hyperuricosuria • Low Urinary pH • Low Urinary Volume
Struvite	5-10%	Coffin Lid	<ul style="list-style-type: none"> • Urine Tract Infection
Cystine	1%	Hexagon	<ul style="list-style-type: none"> • Autosomal Recessive Disease

Due to the mode of action e.g. antispasmodic and diuretic effect, **ROWATINEX®** should facilitate the elimination and expulsion of all types of stones (regardless of chemical composition) and kidney sludge.

3

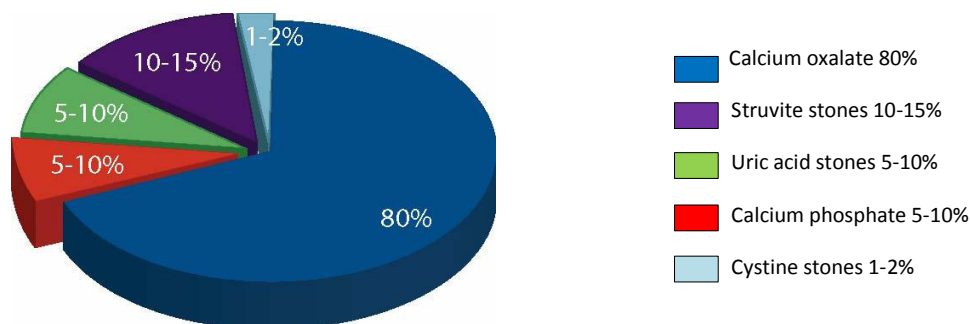
ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

- The majority of stones are calcium based. Calcium oxalate and calcium phosphate stones make up 80% to 90% of all stones.
- Struvite stones make up about 10% to 15% of stones. Struvite stones are mostly found in women who have a urinary tract infection. These stones can grow very large and can block the kidney, ureter or bladder.
- Uric acid stones make up about 5% to 8% of stones or lately even more. Uric acid kidney stones are more common in people with chronically elevated uric acid levels in their blood (hyperuricemia). They can occur with gout or chemotherapy.
- Cystine stones make up about 1% - 2% of stones. Cystine (an amino acid) stones can form in people who have cystinuria. This disorder runs in families and affects both men and women and can be difficult to treat.



4

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

The Solution:

ROWATINEX®

For Removal and Prevention
of **Urinary Stones**

Well established, regulated and trusted **natural**
medical terpene product

5

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

ROWATINEX® Information:

A unique combination of highly purified natural terpenes which have been subjected to extensive pharmacological and clinical research.

Active Ingredients:

Fenchone, Anethole, Alpha-Pinene, Beta-Pinene, Borneol, Cineole and Camphene.

Excipient:

Virgin Olive Oil.

Indications:

Urolithiasis:

ROWATINEX® is used in the treatment of patients with stones in their kidneys or elsewhere in their urinary tract.

Properties:

Promotion of **stone solubility and disintegration**: ROWATINEX® is metabolised to glucuronides which stabilises urinary colloids and increases calcium salt solubility in the urine. These actions reduce the likelihood of stone formation, help to break down already formed stones and facilitate their easier expulsion.

Vasodilatation of tubular capillaries prevents ischaemic degeneration which can upset the colloid balance and thus lead to stone formulation.

Antispasmodic effect: Reduces the force and frequency of smooth muscle spasm and thus eases the pain of renal and ureteric colic.

Antibacterial effect against many bacterial species which can cause infections in the urinary tract.

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

Mode of Action:

ROWATINEX® acts by:

Increasing the solubility of the constituents of renal stones in urine thus helping to dissolve the stones and facilitate their elimination.

Reduces the spasms of the smooth muscles of the urinary tract. These spasms can cause considerable pain and discomfort to patients with stones even when the stones are very small.

The presence of stones in the urinary tract significantly increases the chances of a patient developing a urinary tract infection.

ROWATINEX® has an antibacterial* effect, which helps to reduce the risk of these infections.

Recommended Dosage:

Capsules:

For most patients the best dose is two capsules taken three times daily 30 minutes before meals.

Liquid:

The usual dose is 3-5 drops of liquid 4-5 times daily 30 minutes before meals. In cases of colic, 20-30 drops may be given and repeated, if necessary, 20 minutes later.

*ROWATINEX® is not an antibiotic.

7

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

Safety:

Adverse events are rare with ROWATINEX®.

Occasionally patients complain of slight transient gastric disturbance.

ROWATINEX® should not be used in patients taking oral anticoagulants or other drugs metabolised by the liver where the dose is critical in severe colic or infection and in patients with anuria.

Pregnancy and Lactation:

ROWATINEX® should not be used in pregnant women and in mothers who are breast-feeding.

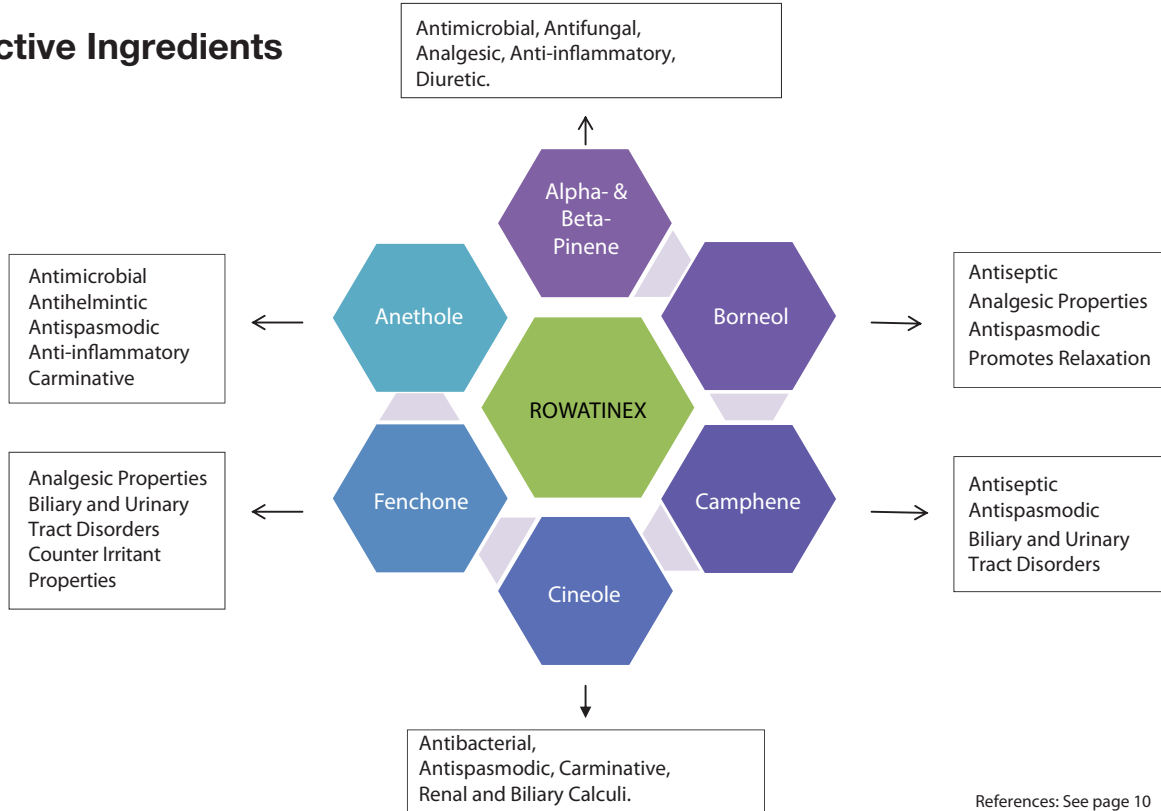
In spite of the fact that the toxicological study gave no cause for concern, it is recommended that ROWATINEX® is not given to women in the first trimester of pregnancy and not given to lactating females.

During the toxicity studies there was no indication to suggest potential carcinogenicity associated with ROWATINEX®.

ROWATINEX®'s safety and efficacy have been widely investigated in a number of clinical trials.

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

Active Ingredients



References: See page 10

9

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.

More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution

Monoterpene References as Published:

- Beatrice Mercer et al: 'The essential oil of turpentine and its major volatile fraction (alpha and beta pinenes): A review'. Universite de Bourgogne, Dijon, France. International Journal of Occupational Medicine and Environmental Health 2009;22(4):331-342.
- PMID23442885: de Silva AC et al; 'Biological activities of alpha and beta pinene enantiomers;' May 2012.
- PMID 25532297; Karapandzova M et al; 'Chemical composition and antimicrobial activity of the essential oils of Pinus peuce (Pinaceae) growing wild in R. Macedonia': November 2014.
- PMID24147201; Dey B, Mitra A; 'Chemo-profiling of eucalyptus and study of its hypoglycemic potential.' October 2013.
- Martindale 37th Edition.
- Clegg R et al; 'The mechanism of cyclic monoterpene inhibition of hepatic 3-hydroxy 3-methylglutaryl coenzyme A reductase in vivo in the rat'; The Journal of Biological Chemistry Vol 257 pp 2294-2299 March 1982.
- Damiao Pergentino de Sousa; 'Analgesic-like activity of essential oils constituents' Molecules 2011; 16 -2233-2252; doi:10.3390/molecules 160322233 March 2011.
- PMID 10861965; Santos FA, Rac VC; 'Anti-inflammatory and antinociceptive effects of 1,8 cineole a terpinoid oxide present in many plant essential oils' Jun 2000.
- Seitz Christian, Dept Urology & Andrology, Medical University, Vienna; 'Medical expulsive therapy of ureteral calculi and supportive therapy after extracorporeal shock wave lithotripsy'. European Urology Supplements 2010;8807-88013.

ROWATINEX® Gastro-Resistant Capsules Soft & Oral Drops Solution



PRODUCT DESCRIPTION

Gastro-Resistant Capsules Soft
Spherical yellow soft gastro-resistant gelatin capsule containing a pale yellow to greenish yellow oil.

Oral Drops Solution
A pale yellow to greenish yellow oral drops solution with an aromatic odour.

<u>Manufacturers:</u>	ROWA Pharmaceuticals Ltd. Newtown Bantry Co. Cork P75 V009 Ireland	ROWA Wagner GmbH & Co. KG, Arzneimittelfabrik Frankenforster Strasse 77 51427 Bergisch Gladbach Germany
-----------------------	---	--







Product of German Origin since 1954

11

ROWATINEX® provides a natural medical solution which dissolves both the URINARY STONES and the PAIN.
More information available on request: ROWA Pharmaceuticals Ltd., Bantry, Co. Cork, P75 V009, Ireland.

www.rowa.ie

Artwork Checklist

Artwork Checklist	Job Description Rowatinex General Info booklet	Version Number 10	Size	Inks							ACCF 17526
	Market	Proof Date 26/01/2016	Cutter Ref.	Colour	Pantone 342	Pantone 360	reflex Blue	Black	Red 032	CMYK	
				Prints On	Front						
				Back							