



Rowatinex[®] Capsules



INFORMATION LEAFLET

Presentation

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

Composition

Each enteric-coated capsule contains -
Pinene ($\alpha + \beta$) 31 mg, Camphene 15 mg, Cineol 3 mg, Fenchone 4 mg,
Borneol 10 mg, Anethol 4 mg.

Uses

Pharmacodynamic

Rowatinex[®] promotes diuresis and relaxes urinary tract spasm, thus assisting the passage of stones. The therapeutic effect of the balanced combination of terpenes reduces urinary tract inflammation stimulating renal blood flow through the kidneys and increasing the output of a less concentrated urine.

Pharmacokinetics

The absorption, distribution, metabolism and excretion were partially analysed for some of the terpenes contained in ROWATINEX (i.e. for α -pinene, β -pinene, camphene, cineol, borneol, anethol). The most important conclusions with respect to the common properties of the single terpenes are that these compounds were rapidly absorbed after oral administration and undergo the first pass metabolism in the liver. Predominantly, terpenes are metabolized via ω -oxidation, O-demethylation and epoxidation pathways and are subsequently conjugated with glucuronic acid. The metabolized terpenes are rapidly eliminated mainly with the urine but partially also by the faeces and via exhalation. The metabolism involving the cytochrome P450 pathways and cytochrome P450 modulating activities of some terpenes may account for possible interactions with other drugs and in case of critical doses and the lacking of interaction studies with ROWATINEX special caution should be advised, despite the missing positive data.

Indications

Rowatinex[®] is indicated for the treatment of urinary tract spasm and inflammation associated with urolithiasis. **Rowatinex[®]** also assists in the dissolution and expulsion of stones in the renal system.

Dosage and Administration

Route of Administration: Oral.

Recommended Dosage:

Adults: Unless otherwise directed by the physician, the usual dose is 1 - 2 capsules three times daily before meals. In case of colic 2 - 3 capsules four - five times daily.

Children 6-14 years: The usual dose is 1 capsule twice daily before meals.

Contra-indications, Warnings, etc.

Contra-indications

There are no known contra-indications to the use of **Rowatinex**[®].

Precautions and Warnings

Liquid intake should be increased during therapy. The product should only be used with caution in patients on anticoagulants or drugs dependent on the liver for metabolism and excretion.

Pregnancy and Lactation

Although no teratogenic effects have been reported, it is advisable that pregnant women should not take **Rowatinex**[®] during the first trimester of pregnancy.

Side Effects

No untoward side effects have been reported.

Symptoms and Treatment of Overdose

If recently ingested the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary.

Storage Conditions

Store below 30°C.

Keep all medicines out of the reach of children.

Package Quantities

Securitainers (bottle) of 50 capsules.

Blister packs of 100 capsules.

Date of revision

This leaflet was last revised in November 2021.

