Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowatinex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

α–Pinene 24.8 mg, β–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 a 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 odor.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjuvant in infections of kidneys and urinary tract.

4.2 Posology and method of administration

Route of Administration: Oral.

Recommended Dosage Schedule:

Adults: The usual dosage is 1-2 capsule 3 times daily before meals

Children aged 6 to 14 years: The usual dosage is 1 capsule twice 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 suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

https://sideeffects.health.gov.il

4.9 Overdose

No cases 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, metabolized 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

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

store below 25°C.

6.5 Nature and contents of container

Rowatinex Capsules are packed in PVC/PCDC/ALUMIIUM blisters.

Rowatinex Capsules are available in tablet containers of 20 and

50 capsules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 LICENSE HOLDER

Megapharm Ltd., 15 Ha'Tidhar street, Ra'anana, Israel.

8 MANUFACTURER

Rowa Pharmaceut. LTD., Ireland

Newtown, Bantry Co. Cork, Ireland

9 ISRAEL LICENSE NUMBER

107-67-20546

10 This leaflet was revised in April 2023 according to MOHs guidelines.