

Rowatinex®

Gastro-resistant Capsules, Soft

α -pinene, β -pinene, camphene, borneol, anethol, fenchone, cineole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Rowatinex® is and what it is used for
2. What you need to know before you take Rowatinex®
3. How to take Rowatinex®
4. Possible side effects
5. How to store Rowatinex®
6. Contents of the pack and other information

1. What Rowatinex® is and what it is used for

Rowatinex® helps to dissolve/break down and remove (disintegrate and eliminate) kidney and urinary tract stones.

Rowatinex® relieves muscle spasm thus reducing the pain of renal and urinary colic. It increases blood flow and reduces inflammation, which could be associated with the presence of kidney stones.

2. What you need to know before you take Rowatinex®

Do not take Rowatinex®:

- if you are allergic to α -pinene, β -pinene, camphene, borneol, anethol, fenchone, cineole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor first before you take Rowatinex®

Do not take Rowatinex® for treatment of urinary stones unless your doctor has confirmed a diagnosis of urinary stones especially in the case of children.

Talk to your doctor or pharmacist before taking Rowatinex® if you are taking medicines to thin your blood or medicines that are broken down by the liver.

Other medicines and Rowatinex®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. These medicines include:

- medicines to thin your blood (oral anti-coagulants e.g. warfarin)
- medicines that are broken down in the liver (ask your doctor for advice on this).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Rowatinex® is unlikely to have any effect on your driving or ability to use machines.

Rowatinex® contains sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) and sunset yellow FCF 85% (E110)

Sodium ethyl parahydroxybenzoate (E215) and sodium propyl parahydroxybenzoate (E217) may cause allergic reactions (possibly delayed).

Sunset yellow FCF 85% (E110) may cause allergic reactions.

3. How to take Rowatinex®

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Rowatinex[®] must only be taken by swallowing the whole capsule. Do not bite or chew the capsules.

The recommended dose for adults is:

1 capsule 4 to 5 times daily before meals.

Use in children and adolescents:

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.

If you take more Rowatinex[®] than you should

If you have taken more capsules than you should, talk to your doctor or pharmacist.

If you forget to take Rowatinex[®]

Do not take a double dose to make up for a forgotten dose. Just take it as soon as you remember. Then go on taking your next dose at the usual time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafty@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rowatinex[®]

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Keep the container tightly closed.

Do not use this medicine after the expiry date which is stated on the label of the container and on the outer carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Rowatinex[®] contains

- The active substances in one gastro-resistant capsule, soft are 24.8 mg α -pinene, 6.2 mg β -pinene, 15.0 mg camphene, 10.0 mg borneol, 4.0 mg anethol, 4.0 mg fenchone, 3.0 mg cineole.

- The other ingredient is virgin olive oil.

- The capsule shell contains gelatine, glycerol 85%, sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217), sunset yellow FCF 85% (E110), quinoline yellow 70% (E104). See section 2 "Rowatinex[®] contains sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) and sunset yellow FCF 85% (E110)".

What Rowatinex[®] looks like and contents of the pack

Rowatinex[®] Capsules are yellow, ball shaped (spherical), soft gelatine gastro-resistant capsules containing a pale yellow to greenish-yellow oral solution with a strong aromatic odour.

Each pack contains 50 or 500 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland.

Tel: +353 27 50077. E-mail: rowa@rowa-pharma.ie

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