

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rowatinex[®] Capsules

Pinene, Camphene, Cineol, Menthone, Menthol, Borneol

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Rowatinex[®] is and what it is used for
2. Before you take Rowatinex[®]
3. How to take Rowatinex[®]
4. Possible side effects
5. How to store Rowatinex[®]
6. Further information

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

Rowatinex[®] contains essential oils that help to dissolve or break down and remove (disintegrating and eliminating) kidney and urinary tract stones.

Rowatinex[®] relieves muscle spasm thus reducing the pain of kidney and urinary colics. Rowatinex[®] is also used to relieve the effects associated with mild urinary tract infections.

2. Before you take Rowatinex[®]

DO NOT take Rowatinex[®] if you are allergic (hypersensitive) to any of the active substances or any of the other ingredients of Rowatinex[®] (see section 6 "Further information" for details).

Take special care with Rowatinex[®]

Rowatinex[®] is not suitable in patients with severe pain (colic), decrease in urine production or severe infection of the urinary tract.

Children and adolescents under 18

Children and adolescents under 18 years of age should not take Rowatinex[®].

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 advise on this)

Taking Rowatinex[®] with food or drink

Rowatinex[®] should be taken on an empty stomach half an hour before meals.

Pregnancy and breast feeding

Ask your doctor or pharmacist for advice before taking any medicine. You should not take Rowatinex[®] in early pregnancy (the first trimester) or if you are breast feeding. No harmful effects on babies have been reported, but the risk is still unknown.

Driving and using machines

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

Important information about some of the ingredients of Rowatinex[®]

Rowatinex[®] contains glycerine (glycerol) which is harmful in high doses. It may cause headache, stomach upset and diarrhoea. This medicine may cause allergic reactions (possibly delayed) as it contains sodium ethyl hydroxybenzoate (E215) and sodium propyl hydroxybenzoate (E217).

3. How to take Rowatinex[®]

Always take Rowatinex[®] exactly as your doctor has told you. You should 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 usual dose for adults:

Take one capsule 3-4 times daily, half an hour before meals.

If you take more Rowatinex[®] than you should

Taking too much Rowatinex® might cause:

- stomach upset (gastric irritation)
- If you have taken more capsules than you should, talk to your doctor or pharmacist immediately

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 stop taking Rowatinex®

Do not stop taking Rowatinex® without discussing this with your doctor.

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

4. Possible Side Effects

Like all medicines, Rowatinex® can cause side effects, although not everybody gets them.

A small number of patients have noted side effects such as:

- slight and temporary stomach upset (gastric disturbance).
- being sick (has been rarely reported).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Rowatinex®

Keep the capsules out of the reach and sight of children.

Do not store above 25°C.

Store in a dry place.

Do not use Rowatinex® after the expiry date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Rowatinex® Capsules contain

- The active substances are: pinene, camphene, cineol, fenchone, borneol and anethol

Each capsule contains:

- pinene [$\alpha+\beta$] 31.0 mg
- camphene 15.0 mg
- cineol 3.0 mg
- fenchone 4.0 mg
- borneol 10.0 mg
- anethol 4.0 mg.

The other ingredients are olive oil (33 mg per capsule)

The capsule shell contains:

- gelatine
- glycerine
- sodium ethylhydroxybenzoate E215
- sodium propylhydroxybenzoate E127
- sunset yellow FD+C, Yellow No. 6 EEC No. 110 85%
- quinoline yellow, EEC No. 104 70%

What Rowatinex® Capsules look like and contents of the pack

Rowatinex® Capsules are yellow, ball shaped (spherical), soft gelatine capsules. The capsules are gastro-resistant. This means they only release the medicine in the intestine, not the stomach.

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.

This medicinal product is authorised in the Member States of the EEA under the following name:

Rowatinex® Capsules

This leaflet was approved in April 2009