

Package leaflet: Information for the user

Rowachol[®]

Gastro-resistant Capsules, Soft

α -pinene, β -pinene, menthol, menthone, camphene, borneol, 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 Rowachol[®] is and what it is used for
2. What you need to know before you take Rowachol[®]
3. How to take Rowachol[®]
4. Possible side effects
5. How to store Rowachol[®]
6. Contents of the pack and other information

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

Rowachol[®] is intended for use in the breaking up (dissolving or disintegrating) or passage (expulsion) of gallstones. Rowachol[®] increases bile production and relaxes the bile ducts. This helps reduce painful spasms of bile ducts. It also makes it easier for any gallstones present to be passed out (expelled) with the bile.

2. What you need to know before you take Rowachol[®]

Do not take Rowachol[®]:

- if you are allergic to α -pinene, β -pinene, borneol, menthol, menthone, camphene, 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 Rowachol[®]

Do not take Rowachol unless your doctor has confirmed a diagnosis of gallstones especially in the case of children.

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

Other medicines and Rowachol[®]

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

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

Rowachol® contains sodium ethyl parahydroxybenzoate (E215) and sodium propyl parahydroxybenzoate (E217)

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

3. How to take Rowachol®

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.

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

The recommended dose for adults is:

1 to 2 capsules three 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 capsule twice daily before meals.

Adolescents aged 14 to 18 years: 1 to 2 capsules three times daily before meals.

If you take more Rowachol® than you should

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

If you forget to take Rowachol®

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 medicine, 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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rowachol®

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 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 Rowachol® contains

- The active substances in one gastro-resistant capsule, soft are 13.6 mg α -pinene, 3.4 mg β -pinene, 32.0 mg menthol, 6.0 mg menthone, 5.0 mg borneol, 5.0 mg camphene, 2.0 mg cineole.
- The other ingredient is virgin olive oil.
- The capsule shell contains gelatine, glycerol 85%, sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217), sodium copper chlorophyllin (100% water soluble). See section 2 "Rowachol® contains sodium ethyl parahydroxybenzoate (E215) and sodium propyl parahydroxybenzoate (E217)".

What Rowachol® looks like and contents of the pack

Rowachol® Capsules are green, ball shaped (spherical), soft gelatine gastro-resistant capsules containing a 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

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