

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rowachol® 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 Rowachol® is and what it is used for
2. Before you take Rowachol®
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4. Possible side effects
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1. What Rowachol® is and what it is used for

Rowachol® contains essential oils that help to dissolve or break up cholesterol-based gallstones. It also reduces the cholesterol content of bile, an important digestive juice that is formed in the liver. This may enable existing gallstones to dissolve and help prevent new gallstones from forming. Rowachol® also increases bile production and relaxes the bile ducts. This helps reduce painful spasms of the bile ducts. It also makes it easier for any gallstones present to be passed out (expelled) with the bile.

Rowachol® Capsules are intended for use in the breaking up (dissolving or disintegrating) or passage (expulsion) of gallstones. Use in combination with a medicine called chenodeoxycholic acid.

2. Before you take Rowachol®

DO NOT take Rowachol®

- if you are allergic (hypersensitive) to any of the active substances
- or any of the other ingredients of Rowachol® (see section 6 "Further information" for details).

Take special care with Rowachol®

- You should be aware that gallstones can sometimes cause yellowing of the skin or whites of the eyes (obstructive jaundice) due to liver or blood problems.
- They can also cause inflammation of the bile duct (ascending cholangitis) and the pancreas (pancreatitis) as well as pain in the stomach (abdominal pain).
- You should tell your doctor at once if you feel that any of these problems are affecting you, especially if you are elderly.

Children and adolescents under 18

Children and adolescents under 18 years of age should not take Rowachol®.

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 advice on this)

Taking Rowachol® with food or drink

Rowachol® 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 Rowachol® 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

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

Important information about some of the ingredients of Rowachol®

- Rowachol® Capsules contain 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 Rowachol®

- Always take Rowachol® exactly as your doctor has told you.
- You should 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 usual dose for adults:

Take 1 – 2 capsules three times daily, half an hour before meals. When you first start treatment, a dose of one capsule three times daily is recommended. Ask your doctor or pharmacist about this.

If you take more Rowachol® than you should

Taking too much Rowachol® might cause:

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

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 stop taking Rowachol®

- Do not stop taking Rowachol® 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, Rowachol® can cause side effects, although not everybody gets them.

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

- belching and a peppermint taste after taking the capsules. (This can be reduced or avoided if you take the capsules on an empty stomach thirty minutes before meals).
- mouth ulcers or soreness of the mouth during treatment with Rowachol®. If you notice this, consult your doctor.

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 Rowachol®

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 Rowachol® 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 Rowachol® Capsules contain**

- The active substances are: pinene, camphene, cineol, menthone, menthol and borneol

Each capsule contains:

- pinene [$\alpha+\beta$] 17.0 mg
- camphene 5.0 mg
- cineol 2.0 mg
- menthone 6.0 mg
- menthol 32.0 mg
- borneol 5.0 mg

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

The capsule shell contains:

- gelatine
- glycerine
- sodium ethyl-hydroxybenzoate E215
- sodium propyl-hydroxybenzoate E127
- sodium copper chlorophyllin water soluble E141

What Rowachol® Capsules look like and contents of the pack

Rowachol® Capsules are green, 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:

Rowachol® Capsules

This leaflet was approved in April 2009