

Package leaflet: Information for the user

Rowatanal[®] Cream

Menthol 1g/100g, Bismuth Subgallate 2g/100g, Zinc Oxide 8g/100g

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse 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 Rowatanal[®] is and what it is used for
2. What you need to know before you use Rowatanal[®]
3. How to use Rowatanal[®]
4. Possible side effects
5. How to store Rowatanal[®]
6. Contents of the pack and other information

ROWA[®]

1 What Rowatanal[®] is and what it is used for

Rowatanal[®] is used to relieve the pain and itching associated with internal and external haemorrhoids (piles), pruritus (symptoms of itching) and irritation around the back passage and other related conditions. It has antiseptic and astringent (cleansing) properties. It relieves the intense itching and burning sensation associated with haemorrhoids.

You must talk to a doctor if you do not feel better or if you feel worse.

2 What you need to know before you use Rowatanal[®]

Do not use Rowatanal[®] if you:

- are allergic to menthol, bismuth subgallate, zinc oxide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Talk to your doctor or pharmacist before using Rowatanal[®] if your piles are bleeding or have been present for some time.

If the condition persists or worsens you should also consult your doctor.

Other medicines and Rowatanal[®]

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

Pregnancy and breast-feeding

This product should not be used during pregnancy and lactation unless considered essential by your physician.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Rowatanal[®] does not normally produce any effects on ability to drive or use machines.

Rowatanal[®] contains glycerol, wool fat and parahydroxybenzoates

This medicine contains glycerol, which may have a mild laxative effect. It contains wool fat, which may cause local skin reactions (e.g. contact dermatitis). It also contains parahydroxybenzoates which may cause allergic reactions (possibly delayed).

3 How to use Rowatanal[®]

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

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Adults only:

Rowatanal[®] is for rectal use only and should not be taken by mouth.

Wash the anal area thoroughly and dry carefully with a very soft towel.

Apply the cream to the affected area 2-3 times daily and after each bowel movement until the condition is controlled.

For internal haemorrhoids use the applicator nozzle provided. Lubricate the applicator nozzle before each application and clean thoroughly after use with a hot solution of detergent. Continue treatment for a few days after the initial signs of improvement.

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

4 Possible side effects

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

Side effects have been reported rarely with use of this and similar products. Side effects include a brief cooling sensation on application of the cream. Sensitivity reactions have been reported very rarely.

Please see Section 2 - Rowatanal[®] contains glycerol, wool fat and parahydroxybenzoates.

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 Rowatanal[®]

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

Do not use this medicine after the expiry date, which is stated on both the outer carton and on the tube after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Rowatanal[®] contains:

- The active substances are menthol, bismuth subgallate and zinc oxide. Each 100g of cream contains 1g menthol, 2g bismuth subgallate and 8g zinc oxide.
- The other ingredients are: hard paraffin, glycerol, wool fat, calcium carbonate, glycerol mono-dioleate, polyoxyethylene-12-cetyl stearyl alcohol, purified water and nipastat which consists of the following parahydroxybenzoates: butyl hydroxybenzoate, ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216) and methyl hydroxybenzoate (E218).

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

Rowatanal[®] Cream is smooth in texture and light yellow in colour.

Rowatanal[®] is available in a 26g tube.

A white cannula nozzle is also included.

Marketing Authorisation Holder and Manufacturer:

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

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