PACKAGE LEAFLET: INFORMATION FOR THE USER

ROWAROLAN CUTANEOUS POWDER

calcium carbonate

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

1. WHAT ROWAROLAN IS AND WHAT IT IS USED FOR

Rowarolan is used for the treatment of the following minor conditions: cuts, abrasions, superficial bed sores and leg ulcers.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ROWAROLAN

Do not use Rowarolan if you:

• are allergic to calcium carbonate or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before using Rowarolan.

Rowarolan should not be ingested. If the powder is accidentally taken by mouth in large quantities, you should contact your doctor or pharmacist.

Pregnancy and breast-feeding

This product should be used in pregnancy and lactation only if considered necessary by your physician. Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO USE ROWAROLAN

Always use 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.

Adults and Elderly:

Clean the wound with running tap water, saline or antiseptic solution. Sprinkle the powder at least three times daily on the affected area or as directed by your doctor or pharmacist. Not recommended for use in children as there is no experience of use in children.

If you forget to use Rowarolan

Use the powder as soon as you remember, then continue as before. If you have any further questions on the use of this product contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ROWAROLAN

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

Keep the container tightly closed in order to protect from moisture. Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the label. 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 Rowarolan contains:

- The active substance is calcium carbonate. 100g of powder contains 90.0g calcium carbonate.
- The other ingredients are silica colloidal anhydrous and talc.

What Rowarolan looks like and contents of the pack

Rowarolan is an off-white odourless fine cutaneous powder. Rowarolan is available in a 20g polypropylene jar, which is fitted with a sprinkler insert, a stopper label and a cap.

Marketing Authorisation Holder and Manufacturer:

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

This leaflet was last revised in August 2020.