Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rowarolan Cutaneous Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g of Rowarolan Powder contains calcium carbonate 90.0g.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Powder.
An off white odourless fine cutaneous powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

Route of Administration: Topical

Recommended Dosage Schedule:

Adults and Elderly: Sprinkle the powder at least three times daily on the affected area as prescribed by the physician.
Use in children/adolescents: There is no experience of use in children

4.3 Contraindications

Hypersensitivity to the active ingredient or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Rowarolan Powder is not to be ingested.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of Rowarolan Powder in pregnant women. It is unknown whether Calcium Carbonate is excreted in human breast milk. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Rowarolan Powder should be made taking into account the benefit of breast-feeding to the child and the benefit of Rowarolan Powder to the woman. (See Section 5.2).

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Rowarolan Powder contains various minerals including trace elements. These components possess non-allergic and other therapeutically effective properties. The powder does not irritate healthy skin and by neutralising tissue acidosis, pain is relieved.

5.2 Pharmacokinetic properties

Rowarolan Powder is not absorbed.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal anhydrous silica
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.

6.5 Nature and contents of container

Rowarolan powder is packed in 20g polypropylene jars, which are fitted with sprinkler inserts, stopper labels and caps.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Limited
Newtown
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/046/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th February 1999

Date of last renewal: 5th February 2009

10 DATE OF REVISION OF THE TEXT

September 2020