Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pedamed 100 mg/g Cutaneous Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of powder contains 100 mg zinc undecylenate equivalent to zinc undecylenate 10% w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous powder
Fine, white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention of athlete's foot and other fungal skin infections.

For the elimination of foot odours and antiperspirant effect.

4.2 Posology and method of administration

After cleansing and drying the affected area, Pedamed Powder should be applied twice daily and rubbed in gently. For optimum effectiveness the powder should be used with an appropriate anti-fungal cream. Treatment should be continued for one week after all signs of infection have disappeared.

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Do not use on broken skin.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

No information available.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Skin irritation can occur occasionally to some of the ingredients. If this occurs, use of the product should be discontinued.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc Undecylenate is an anti-fungal agent.

5.2 Pharmacokinetic properties

No information given.

5.3 Preclinical safety data

No information given.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Zinc oxide
Alum
Allantoin
Chlorhexidine hydrochloride
Levomenthol
Talc
Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 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

Multidose, tubular white polypropylene bottle with polypropylene sifter-top cap and outer flip-cap with child-resistant tamper evident seal. Contains 65g of Pedamed 100 mg/g Cutaneous Powder.

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

Phoenix Healthcare Ltd
Suite 12 Bunkilla Plaza
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Clonee
Co Meath
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1721/007/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 August 1986

Date of last renewal: 26 August 2006

10 DATE OF REVISION OF THE TEXT

October 2021