

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Pedamed 100 mg/g Cream

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients: Bronopol 0.500 mg/g.

Ethyl, Methyl and Propyl parahydroxybenzoates (E214, E218, E216) 1.5 mg/g.

For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cream

Smooth, white cream.

## 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 Cream should be applied twice daily and rubbed in gently. For optimum effectiveness the cream should be used with an appropriate anti-fungal powder. 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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

### **4.9 Overdose**

Not applicable.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Zinc Undecenoate 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  
Light liquid paraffin  
White soft paraffin  
Sorbitol solution (70 per cent) (non-crystallising)  
Macrogol stearate  
Hydrogenated Vegetable Glyceride  
Ethyl, Methyl and Propyl parahydroxybenzoates (E214, E218, E216)  
Bronopol  
Purified water

### **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, tamper-proof, air-tight, collapsible aluminium tube with a HDPE closure. The tube is internally coated with an epoxyphenolic liner and has a polyurethane external varnish. Each tube contains 30g Pedamed Cream.

**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  
Bracetown Business Park  
Clonee  
Co Meath  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA1721/007/001

**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