

## Summary of Product Characteristics

### 1. NAME OF THE MEDICINAL PRODUCT

Dermamist 10% w/w Dry Skin Spray

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

White Soft Paraffin 10% w/w.

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Cutaneous Spray, solution (cutaneous spray)

A cutaneous spray delivering white soft paraffin as a clear colourless spray by means of a pressurised aerosol.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Treatment of dry skin conditions including pruritus (itching and dryness) of the elderly eczema, and ichthyosis (dry scaly skin).

#### 4.2 Posology and method of administration

##### Adults, children and the elderly:

Shake before use. Bathe or shower for not more than ten minutes.

Pat dry and apply spray without delay. Do not spray on face. Spray from a distance of approximately 8 inches. Spray away from the face and move the can while spraying to achieve a very light coverage of the body. Spray sparingly; over application may cause the skin to feel oily.

#### 4.3 Contraindications

Hypersensitivity to any of the ingredients.

#### 4.4 Special warnings and precautions for use

For external use only.

Keep out of reach of children.

Do not spray on face.

Use in a ventilated area.

Avoid inhalation.

Guard against slipping.

Discontinue use if the condition is made worse.

Do not apply to broken skin.

#### 4.5 Interactions with other medicinal products and other forms of interaction

None.

#### **4.6 Pregnancy and lactation**

Can be used.

#### **4.7 Effects on ability to drive and use machines**

Not relevant.

#### **4.8 Undesirable effects**

Not relevant.

#### **4.9 Overdose**

None.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Emollients are fats or oils used for their local action on the skin and, occasionally, the mucous membranes. These oleaginous substances, also known as occlusive agents and humectants, are employed as protectives and as agents for softening the skin and rendering it more pliable. White soft paraffin forms an effective occlusive lipid film. The mechanism of action is by occluding water loss from the outer layer of skin.

#### **5.2 Pharmacokinetic properties**

White soft paraffin exerts its physiological effects by forming an occlusive layer on the surface of the skin. It is effective because it is not subject to absorption or subsequent distribution in the body, excretion or metabolism. Pharmacokinetic particulars are not appropriate in these circumstances.

#### **5.3 Preclinical safety data**

No relevant pre-clinical data has been generated.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Liquid paraffin  
Medium chain triglycerides  
Butane 40 (butane: isobutane: propane)

#### **6.2 Incompatibilities**

Not Applicable.

#### **6.3 Shelf life**

5 years.

#### **6.4 Special precautions for storage**

Do not store above 25°C.

Extremely flammable.

Protect from sunlight and do not expose to temperatures exceeding 50°C.

Do not pierce or burn even when empty.

Do not spray on a naked flame or any incandescent material.

Keep away from sources of ignition – no smoking.

#### **6.5 Nature and contents of container**

Pressurised aluminium aerosol can. Pack sizes: 50ml, 75ml, 100ml, 125ml, 150ml, 200ml, 250ml, 300ml, 400ml and 500ml.

Not all pack sizes may be marketed.

#### **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**

Alliance Pharmaceuticals Limited  
Bath Road  
Chippenham  
Wiltshire SN15 2BB  
England

### **8. MARKETING AUTHORISATION NUMBER**

PA 943/15/1

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 04 April 1997

Date of last renewal: 04 April 2007

### **10. DATE OF REVISION OF THE TEXT**

August 2007