

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 10.0% 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.

Patients being dispensed or treated with large quantities (> 100g) of any paraffin based product should be advised to regularly change clothing or bedding impregnated with the product and keep away from naked flames as there is a fire hazard.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, 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

April 2010