

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Dermamist

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

White Soft Paraffin BP 10.0% w/w.

3. PHARMACEUTICAL FORM

Pressurised aerosol

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of dry skin conditions including eczema, ichthyosis and pruritus of the elderly.

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 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

Dermamist UK SPC 002

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 BP
Fractionated coconut oil BP
Butane 40 (butane: isobutane: propane) HSE

6.2 Incompatibilities

None

6.3 Shelf life

60 months.

6.4 Special Precautions for Storage

Store below 25°C. Pressurised container. Highly flammable, Protect from sunlight and do not puncture, burn or expose to temperatures over 50°C even when empty. Do not spray on a naked flame or any incandescent material.

6.5 Nature and contents of container

Pressurised aerosol. Pack sizes 50 ml, 250 ml, 75 ml, 150 ml, 200 ml, 300 ml, 400 ml, and 500 ml. (75 ml, 150 ml, 200 ml, 300 ml, 400 ml, and 500 ml are currently not 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 instructions for use or handling.

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Limited
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SN15 2BB

8. MARKETING AUTHORISATION NUMBER

PL 16853/0098

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/03/94

10. DATE OF REVISION OF THE TEXT

23rd June 2009