SUMMARY OF PRODUCT CHARACTERISTICS

1  NAME OF THE MEDICINAL PRODUCT

Zerolatum Emollient Medicinal Bath Oil

2.  QUALITATIVE AND QUANTITATIVE COMPOSITION

Liquid Paraffin BP 65% w/w, Acetylated Wool Alcohols 5% w/w

3.  PHARMACEUTICAL FORM

A colourless to pale yellow oily liquid

4.  CLINICAL PARTICULARS

4.1 Therapeutic Indications

For topical administration for the symptomatic relief of contact dermatitis, atopic dermatitis, senile pruritus, ichthyosis and related dry skin disorders

4.2 Posology and Method of Administration

Adults, including elderly:

Add 15-20ml to a standard bath of water (8 inches deep). Immerse and cover the affected areas with the bath water and soak for 10-20 minutes. Pat dry with a towel.

Infants and children:

Add 5-10ml to a small bath or wash basin of water. Immerse and cover the affected areas with the bath water and soak for 10-20 minutes. Alternatively, repeatedly gently sponge over the affected areas. Pat dry with a towel.

There is no differentiation between the dosage quantities for the symptomatic relief of the conditions listed.
4.3 Contra-Indications

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Take care not to slip in the bath or shower. Surfaces that have been in contact with the product should be cleaned with a proprietary detergent.

If this product comes into contact with dressings and clothes, it can be easily ignited with a naked flame. Patients are advised to avoid fire when using Zerolatum Emollient Medicinal Bath Oil.

4.5 Interactions with other Medicinal Products and other Forms of Interaction

None known

4.6 Pregnancy and Lactation

The constituents are not percutaneously absorbed or toxic if ingested. There is no evidence of safety of the drug used in pregnancy or lactation, but the active constituents have been in widespread use and in similar preparations for many years without apparent ill consequence.

4.7 Effects on Ability to Drive and Use Machines

None known

4.8 Undesirable Effects

Contact sensitivity reactions may occur occasionally in patients sensitised to one or more of the constituents e.g. to acetylated wool alcohols. These occur infrequently causing mild irritation and are not serious. Do not repeat treatment with such patients.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Accidental ingestion may result in a purgative action due to the liquid paraffin and the oily nature of the product. Treat symptomatically. Fluid and electrolyte replacement may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Liquid Paraffin has emollient, humectant and lubricant properties. The acetylated wool alcohols (Crodalan LA) are a lipophilic emollient preparation lacking some of the physical disadvantages of lanolins and derivatives eg stickiness and waxiness. Isopropyl myristate is a diluent for oily preparations and confers improved feel and spread. Volpo L3 Special is a dispersant and emulsifier developed for specific use in bath oils. The blended preparation has emollient and lubricant properties and disperses readily in bath water. The product is dye and fragrance free.

5.2 Pharmacokinetic Properties

The active constituents are not absorbed percutaneously therefore pharmacokinetic particulars are not relevant.

5.3 Pre-clinical Safety Data

None available, however both active constituents have been in widespread use both individually and in similar preparations without apparent ill consequence.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Isopropyl myristate and Volpo L3 Special.
6.2 **Incompatibilities**

None known.

6.3 **Shelf-Life**

36 months.

6.4 **Special Precautions for Storage**

Do not store above 25°C.

6.5 **Nature and Content of Container**

High density polyethylene bottle with plastic closure to fit.

Pack size: 150ml, 250ml, 350ml, 500ml and 1000ml.

6.6 **Instruction for Use, Handling and Disposal**

For topical administration only.

7 **MARKETING AUTHORISATION HOLDER**

ZeroDerma Ltd
Linthwaite Laboratories
Linthwaite
Huddersfield
HD7 5QH
United Kingdom

8 **MARKETING AUTHORISATION NUMBER(S)**

PL 18962/0009
9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/02/2011

10  DATE OF REVISION OF THE TEXT

23/12/2014