



SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. Trade name of the Medical Product

Balmndol Bath Oil, Infaderm After Bath Oil, Infaderm Therapeutic Oil, Imoderm Therapeutic Oil.

2. Qualitative and Quantitative Composition

The solution contains Almond Oil BP 30% w/w and Light Paraffin BP 69.595% w/w

3. Pharmaceutical Form

Bath additive.

Clinical Particulars

4.1. Therapeutic Indications

As an adjunct therapy for dermatoses characterised by dry, scaly or fissured skin

Including:

- A) Atopic eczema
- B) Senile pruritis
- C) Ichthyosis
- D) Neurodermatitis
- E) Psoriasis
- F) Eczema Craquele
- G) Contact Dermatitis

4.2. Posology and Method of Administration

Dosage:

Adults, elderly and children:

Baths- using enclosed measure, add 15-30mls of Balmndol to 6-8 inches of warm water. Stir to ensure even dispersal over the surface of the water.

Approximately half of this measure is appropriate for babies and children bathing in smaller baths.

As an emollient : Apply directly to the skin, and rub in.

4.3. Contra-indications

None.

4.4. Special Warnings and Precautions for Use

Discontinue use if product causes irritation.

4.5. Interactions with other Medicaments and other forms of Interaction

None.

4.6. Pregnancy and Lactation

No special precautions.

4.7. Effects on Ability to Drive and Use Machines

None expected.

4.8. Undesirable Effects

None expected.

4.9. Overdose

None stated.

Pharmacological Properties

5.1. Pharmacodynamic Properties

Balmandol has properties of an emollient when applied directly to the skin.

When used in the bath, the oil envelopes the patient on leaving the bath, thereby delaying the evaporation of the water absorbed during the bath.

5.2. Pharmacokinetic Properties

None stated.

5.3. Preclinical Safety Data

No further relevant data.

Pharmaceutical Particulars

6.1. List of Excipients

Poloxamer NF
Cyclomethicone
Butylated Hydroxyanisole BP

Citric Acid Monohydrate BP
Chemical E486

6.2. Incompatibilities

None known.

6.3. Shelf Life

The shelf life expiry date for this product shall not exceed three years from the date of its manufacture.

6.4. Special Precautions for Storage

None.

6.5. Nature and Contents of Container

Coloured PVC bottle fitted with a polyethylene plug and polypropylene cap or a polyethylene cap containing 35, 50, 150, 225, 250 or 500ml.

6.6. Instruction for Use/Handling

None stated.

Administrative Data

7. Marketing Authorisation Holder

Goldshield Group Plc
NLA Tower
Croydon CR0 0XT

Trading as Goldshield Pharmaceutical
NLA Tower
Croydon CR0 0XT

8. Marketing Authorization Number

PL 10972/0071

9. Date of First Authorisation/Renewal of Authorisation

8 January 1996

10. Date of (Partial) Revision of the Text

June 2000