Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diprobath 46% w/w and 39% w/w Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light Liquid Paraffin 46.0% w/w
Isopropyl Myristate 39.0% w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Bath additive
Clear, colourless, oily liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of dry skin conditions and other hyperkeratoses including those associated with dermatitis and eczema.

4.2 Posology and method of administration

To be applied externally, diluted in a bath of water.

Adults including elderly patients: 25 ml or approximately 2.5 capfuls to be diluted in a bath of water (100:1 approximately). For particularly dry skin, the quantity of oil emollient may be doubled.

10ml or one capful is sufficient for children's bath.

Frequency and duration of bathing will depend on the type and severity of the conditions, but generally 2 to 3 baths should be taken weekly.

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

As Diprobath deposits a film of oil over the skin, care should be taken to avoid slipping in the bath. The following warning will appear on the label:
"Take care when entering or leaving the bath which may be more slippery than usual".

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Light liquid paraffin and Isopropyl Myristate are known emollients and their combination in Diprobath provides a suitable bathing additive to reduce moisture loss.

5.2 Pharmacokinetic properties

Pharmacokinetic principles are not involved due to direct topical application.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Laureth - 4
(lauromacrogol)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

500 ml: natural opaque high-density polyethylene (HDPE) single neck bottle with a polypropylene screw cap. Mounted in the cap is a polyethylene liner containing a polytetrafluoroethylene (PTFE) venting disc.

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

Merck Sharp & Dohme Ireland (Human Health) Limited
Red Oak North
South County Business Park
Leopardstown
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 1286/36/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authroisation: 14 March 1995

Date of last renewal: 01 January 2007

10 DATE OF REVISION OF THE TEXT

April 2014