Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diprobase Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipients include: Chlorocresol 0.10% w/w and Cetostearyl Alcohol 7.20% w/w
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
Smooth uniform white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Diprobase Cream is an emollient, moisturising and protective cream for the follow-up treatment with topical steroids or in spacing such treatment. It may also be used as diluent for topical steroids. Diprobase Cream is recommended for the symptomatic treatment of red inflamed, damaged, dry or chapped skin, the protection of raw skin areas and as a pre−bathing emollient for dry/eczematous skin to alleviate drying areas.

4.2 Posology and method of administration

Adults and Children :

The cream should be applied to the dry skin areas as often as is required and rubbed well into the skin.

4.3 Contraindications

There are no absolute contraindications to the use of the cream other than hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Diprobase Cream contains Chlorocresol which may cause allergic reactions and Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Skin reactions including pruritus, rash, erythema, skin exfoliation, burning sensation, hypersensitivity, pain, dry skin and bullous dermatitis have been reported with product use.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Diprobase Cream contains no active ingredients and has no pharmacological action. The ingredients provide emollient, moisturising action on dry or chapped skin.

5.2 Pharmacokinetic properties

Not applicable due to topical administration and direct action on the skin.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Macrogol Cetostearyl ether
Cetostearyl alcohol
Liquid paraffin
White soft paraffin
Phosphoric acid
Sodium dihydrogen phosphate
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Aluminium Tubes: 5 years

Plastic jar with pump: 3 years

6.4 Special precautions for storage

Store below 25^{o}C.

6.5 Nature and contents of container

15g, 50g, and 100g aluminium epoxy lined membrane tubes with plastic caps.

A 500g polypropylene jar with a polyethylene follower plate and a pump system.The pump system consists of a polypropylene pump cylinder, a polypropylene head, a polypropylene pump body and a polyethylene piston with a glass valve and a polyethylene valve.

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.
Any unused product or waste material should be disposed of in accordance with the local requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1410/076/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th October 1983

Date of last renewal: 5th October 2008

10 DATE OF REVISION OF THE TEXT

April 2015