SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Diprobase Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

No pharmacologically active components.

3 PHARMACEUTICAL FORM

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

None stated.

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

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 SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol; Macrogol Cetostearyl Ether (Cetomacrogol); Cetostearyl alcohol; Liquid paraffin; White soft paraffin; Phosphoric acid; Sodium dihydrogen phosphate; Sodium hydroxide; Purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

15, 50 and 100gm aluminium tubes - 60 months

500gm polypropylene jar with pump presentation – 36 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

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

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

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8 MARKETING AUTHORISATION NUMBER(S)

PL 00010/0658

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 April 1996

10 DATE OF REVISION OF THE TEXT

21/03/2018