Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Diprobase Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment.
Smooth, uniform white ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Diprobase Ointment is an emollient, moisturising and protective ointment for the follow-up treatment with topical steroids or in spacing such treatment. It may also be used as diluent for topical steroids. Diprobase Ointment 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 ointment should be thinly applied to cover the affected area completely, massaging gently and thoroughly into the skin. Frequency of application should be established by the physician. Generally, Diprobase Ointment can be used as often as required.

4.3 Contraindications

Hypersensitivity to any of the components of the ointment is a contraindication to its use.

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 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 Ointment contains no active ingredients and has no pharmacological action. The ingredients have an emollient 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

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin
Liquid Paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years (tube presentations)
3 years (500g plastic jar with screw cap)

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

5g, 50g and 100g: Epoxy lined aluminium tubes with plastic caps.
500g: White polypropylene jar closed with a white tamper-evident low density polyethylene screw cap.
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

PA1410/076/001

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