

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Doublebase Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Isopropyl Myristate 15% w/w

Liquid Paraffin 15% w/w

For excipients see Section 6.1

3 PHARMACEUTICAL FORM

White opaque gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A highly emollient and protective hydrating base for regular first-line treatment and prophylaxis of dry or chapped skin conditions which may also be pruritic (itchy) or inflamed. Doublebase may also be used as an adjunct to other topical treatments.

4.2 Posology and method of administration

For external use only.

For adults, the elderly, infants and children.

- Apply Doublebase to the affected areas as often as necessary.

For best results use a few gentle strokes to smooth Doublebase across the skin in the same direction as hair growth. If necessary, allow time for any excess to soak in. Do not rub vigorously.

- Doublebase may also be applied before washing, showering or having a bath to prevent further drying of the skin.

If additional topical treatments are being used on the same skin areas, Doublebase should be applied between these applications.

4.3 Contraindications

Do not use in cases of known sensitivity to any of the ingredients

4.4 Special warnings and precautions for use

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

No special precautions

4.7 Effects on ability to drive and use machines

No special precautions

4.8 Undesirable effects

Although Doublebase has been specially formulated for use on dry, problem or sensitive skin, local skin reactions can occur in rare cases. In this event, treatment should be discontinued.

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

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The oily ingredients, isopropyl myristate and liquid paraffin, encourage rehydration and softening of dry skin by forming an occlusive barrier within the skin surface, thus reducing drying from evaporation of water that diffuses from the underlying layers.

5.2 Pharmacokinetic properties

Because Doublebase is designed to deliver the emollient ingredients into the stratum corneum when gently applied to areas of dry skin, it is relatively non-greasy despite its high oil content.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

Carbomer

Sorbitan laurate

Trolamine

Phenoxyethanol

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C

Do not freeze

6.5 Nature and contents of container

PVC bottle (1 kg and 500 g) with polypropylene metering pump.

Polyethylene laminate tube (100 g and 25 g) with polypropylene screw cap.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited

T/A Dermal Laboratories

Tatmore Place

Gosmore
Hitchin
Hertfordshire, SG4 7QR
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PL 00173/0183

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

21/03/2001 / 13/07/2006

10 DATE OF REVISION OF THE TEXT

20/12/2019