

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Doublebase Emollient Wash Gel

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Isopropyl Myristate	15% w/w
Liquid Paraffin	15% w/w

For full list of excipients see section 6.1

### **3 PHARMACEUTICAL FORM**

Gel

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. The product may also be used as an adjunct to other topical treatments.

#### **4.2 Posology and method of administration**

For adults, the elderly and children. For cutaneous use only. Use regularly and as often as necessary.

- Use the product to gently wash the skin.
- Rinse off and pat the skin dry using a soft towel. (avoid rubbing as this can irritate the skin).

#### **4.3 Contraindications**

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

#### **4.4 Special warnings and precautions for use**

Take care not to slip if using the product in the bath or shower. Surfaces that have been in contact with the product should be cleaned with a proprietary detergent.

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 the product 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](http://www.mhra.gov.uk/yellowcard).

#### **4.9 Overdose**

Not applicable.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC code: D02A, emollients and protectives.

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. The product is also suitable for use as a soap substitute owing to the presence of a non-ionic emulsifier (cetomacrogol).

## **5.2 Pharmacokinetic properties**

Because the product 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**

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Glycerol E422

Carbomer

Sorbitan Laurate

Trolamine

Phenoxyethanol

Macrogol cetostearyl ether (cetomacrogol)

Purified Water

## **6.2 Incompatibilities**

None known

## **6.3 Shelf life**

25g polyethylene laminate tube with polypropylene screw cap: 24 months

200g HDPE bottle with polypropylene/LDPE pump dispenser: 18 months

**6.4 Special precautions for storage**

Do not store above 25°C

Do not freeze.

**6.5 Nature and contents of container**

HDPE bottle (200 g) with polypropylene/LDPE pump dispenser.

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

**6.6 Special precautions for disposal**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Diomed Developments Limited

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**8 MARKETING AUTHORISATION NUMBER(S)**

PL 00173/0402

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

15/11/2024

**10 DATE OF REVISION OF THE TEXT**

15/11/2024