

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Ultrabase®

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

White Soft Paraffin 10.0 %w/w

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Cream

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For general use as:

- an emollient
- a diluent for dermatological preparations and
- a vehicle for various dermatological medicaments.

Additionally, it may be alternated with topical corticosteroids when the latter are being gradually withdrawn, and may be continued alone after complete withdrawal of the topical corticosteroid.

### 4.2 Posology and method of administration

For topical administration as required.

### 4.3 Contraindications

Hypersensitivity to any of the components of Ultrabase.

### 4.4 Special warnings and precautions for use

Ultrabase contains stearyl alcohol which may cause local skin reactions e.g. (contact dermatitis).

Ultrabase contains methyl parahydroxybenzoate (methyl paraben) [E218] and propyl parahydroxybenzoate (propyl paraben) [E216]. These ingredients may cause allergic reactions (possibly delayed).

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 Fertility, pregnancy and lactation**

None stated.

#### **4.7 Effects on ability to drive and use machines**

None known.

#### **4.8 Undesirable effects**

Hypersensitivity skin reactions including erythema and pruritus.

##### 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, website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

Not applicable.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

The Ultrabase cream formulation has good emollient properties.

### **5.2 Pharmacokinetic properties**

None stated.

### **5.3 Preclinical safety data**

There are no preclinical safety data which could be of relevance to the prescriber and which are not already included in other relevant sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Polyoxyl 40 stearate [E431]

Liquid paraffin

Stearyl alcohol

Carbomer

Sodium hydroxide

Methyl parahydroxybenzoate (methyl paraben) [E218]  
Propyl parahydroxybenzoate (propyl paraben) [E216]  
Disodium edetate  
Purified water  
Citrus-rose perfume oil

## **6.2 Incompatibilities**

None known.

## **6.3 Shelf life**

5 years

## **6.4 Special precautions for storage**

Not applicable.

## **6.5 Nature and contents of container**

This product is available in collapsible aluminium tubes (10 g or 50 g) and polypropylene jars (500 g).

Also available in a polypropylene pump dispenser (500 g) and a pump dispenser composed of polyethylene and polypropylene (50 g, 200 g or 500 g).

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

Keep out of the reach of children.

## **7 MARKETING AUTHORISATION HOLDER**

Derma UK Ltd  
The Toffee Factory  
Lower Steenbergs Yard, Quayside  
Ouseburn, Walker Rd  
Newcastle upon Tyne  
Tyne and Wear NE1 2DF  
UK

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 19876/0014

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

02/06/1972 / 22/05/2007

**10 DATE OF REVISION OF THE TEXT**

15/05/2019