

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Cetraben Emollient Cream

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

White Soft Paraffin 13.2% w/w

Light Liquid Paraffin 10.5% w/w

Excipient(s) with known effect

Butylparaben 0.022% w/w

Ethylparaben 0.014% w/w

Methylparaben 0.057% w/w

Emulsifying wax 5.2% w/w

(Containing Sodium laurilsulfate 0.49% w/w and Cetostearyl alcohol)

Cetostearyl alcohol 6.21% w/w

For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Cream.

A thick white cream with the characteristic odour of paraffin oil.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Cetraben Emollient Cream is an emollient, moisturising and protective cream for the symptomatic relief of red, inflamed, damaged, dry or chapped skin, especially when associated with endogenous or exogenous eczema.

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

Cetraben Cream should be applied to the dry skin areas as often as required and rubbed in.

### **4.3 Contraindications**

Hypersensitivity to any of the ingredients.

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

This medicine contains Cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 0.49% w/w Sodium laurilsulfate per application which may cause local skin reactions (such as stinging or burning sensations or increase skin reactions caused by other products when applied on the same area.

This medicine contains parahydroxybenzoates which 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**

No special precautions are required.

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

None.

### **4.8 Undesirable effects**

Very rarely, mild allergic skin reactions including rash and erythema have been observed, in which case use of the product 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) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

#### **4.9 Overdose**

None reported.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC Code: D02A X (Other Emollients and Protectives).

The ingredients of Cetraben Cream have an emollient, moisturising and protective properties.

### **5.2 Pharmacokinetic properties**

Cetraben cream acts only on the skin.

### **5.3 Preclinical safety data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Emulsifying wax (Containing Cetostearyl alcohol and Sodium laurilsulfate)  
Cetostearyl Alcohol  
Glycerin (E422)  
Butylparaben  
Methylparaben (E218)  
Ethylparaben (E214)  
Propylparaben  
Phenoxetol  
Citric Acid  
Purified water

### **6.2 Incompatibilities**

None known.

**6.3 Shelf life**

Three years

**6.4 Special precautions for storage**

Do not store above 25°C.

**6.5 Nature and contents of container**

Polypropylene jars with a pump dispenser of 1050g, 500g, 150g and 50g,  
polyethylene screw capped jars\* or tubes of 125g,  
polyethylene screw capped jars or tubes of 50g

\* not currently marketed.

**6.6 Special precautions for disposal**

Not applicable.

**7 MARKETING AUTHORISATION HOLDER**

Genus Pharmaceuticals

Linthwaite,

Huddersfield,

HD7 5QH, UK

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 06831/0259

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

21/09/2006

**10 DATE OF REVISION OF THE TEXT**

04/10/2019