

# Cetomacrogol Cream BP 1988 Formula A

Summary of Product Characteristics Updated 12-Sep-2019 | Thornton & Ross Ltd

## 1. Name of the medicinal product

Cetomacrogol Cream BP 1988 Formula A

## 2. Qualitative and quantitative composition

Macrogol Cetostearyl Ether 22      1.8% w/w

## 3. Pharmaceutical form

Cream.

## 4. Clinical particulars

### 4.1 Therapeutic indications

For external application for use as an emollient, and for use as a diluent in medicinal external preparations.

### 4.2 Posology and method of administration

Topical

#### Recommended dose and dosage schedule

To be used as prescribed by a registered medical practitioner or counter prescribed by a registered pharmacist.

The product is suitable for use by adults, children and the elderly.

Dosage: as prescribed by the medical practitioner or pharmacist.

### 4.3 Contraindications

Sensitivity to chlorocresol.

### 4.4 Special warnings and precautions for use

For external use only.

Keep all medicines away from children.

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.

Store below 25°C. Do not allow to freeze.

The diluted cream should be used within 2 weeks of preparation.

### 4.5 Interaction with other medicinal products and other forms of interaction

None known.

### 4.6 Fertility, pregnancy and lactation

No special precautions regarding this vehicle.

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

None known.

### 4.8 Undesirable effects

None known.

#### **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

Not applicable.

## **5. Pharmacological properties**

### **5.1 Pharmacodynamic properties**

The product has an emollient effect.

### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

None.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Cetostearyl alcohol

Chlorocresol

Liquid Paraffin

Paraffin White Soft

Water Purified

### **6.2 Incompatibilities**

Macrogol cetostearyl ether is incompatible with phenols and reduces the antibacterial activity of quaternary ammonium compounds.

### **6.3 Shelf life**

500g: 36 months unopened.

### **6.4 Special precautions for storage**

Store below 25°C. Do not allow to freeze.

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

500g: polypropylene jar and lid.

### **6.6 Special precautions for disposal and other handling**

None.

## **7. Marketing authorisation holder**

Thornton & Ross Ltd.

Linthwaite Laboratories

Huddersfield

HD7 5QH

## **8. Marketing authorisation number(s)**

PL 00240/0014

## **9. Date of first authorisation/renewal of the authorisation**

31.05.74 / Last renewed 25.11.98

## **10. Date of revision of the text**

11/09/2019

## **Company Contact Details**

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