

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Cetanorm Cream  
Vantage Pharmacy Antiseptic Cream  
Savoy First Aid Cream

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

Each 100g of cream contains the following active ingredients:

|                       |         |
|-----------------------|---------|
| Benzalkonium Chloride | 0.10 G  |
| Cetrimide             | 0.40 G  |
| Chlorbutanol          | 0.10 G  |
| Aldioxa               | 0.375 G |

### **3 PHARMACEUTICAL FORM**

Cream, for topical application.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

External treatment of cuts, scratches, abrasions, small wounds, and napkin rash.

#### **4.2. Posology and Method of Administration**

Apply sparingly two or three times per day ensuring the area is first free from soap.

No distinction is made between adults, children and the elderly.

#### **4.3. Contra-Indications**

Known sensitivity to any of the ingredients.

#### **4.4. Special Warnings and Special Precautions For Use**

Ensure the skin is washed free from soap before application.

#### **4.5. Interaction with other Medicinal Products and other Forms of Interaction**

Incompatible with soap and other anionic detergents.

#### **4.6. Pregnancy and Lactation**

The product is considered safe for use during pregnancy when used as directed, but medicaments should only be used at in pregnancy when anticipated benefits exceed the risks.

#### **4.7. Effects on Ability to Drive and Use Machines**

None

#### **4.8. Undesirable Effects**

Local irritation may occur.

#### **4.9 Overdose**

Overdose is unlikely when used as directed. If someone accidentally swallows this cream medical advice should be sought immediately.

### **5. Pharmacological Properties**

#### **5.1. Pharmacodynamic Properties**

Allantoin and its derivatives stimulate tissue and accelerate wound healing. They appear to have a keratin dispersing activity.

The quaternary ammonium compounds have detergent, and gram positive and gram negative bactericidal activity.

Chlorbutol has antibacterial and antifungal activity. It also has a mild local anaesthetic action.

## **5.2. Pharmacokinetic Properties**

When used as directed systemic absorption is negligible.

## **5.3. Pre-clinical Safety Data**

None stated.

# **6. Pharmaceutical Particulars**

## **6.1. List of Excipients**

The cream also contains Cetyl Alcohol, Polychol 15, Wool Alcohols, Chlorhexidine Solution, Nonoxinol '9' and Deionised Water.

## **6.2. Incompatibilities**

The product is not intended to be diluted before use.

## **6.3. Shelf Life**

36 months in original container, 1 month after first opening

## **6.4. Special Precautions for Storage**

Store between 4°C and 25°C.

## **6.5. Nature and Contents of Container**

Collapsible Aluminium Tube containing 15g or 25g of product.

**6.6. Instructions for Use, Handling and Disposal**

None

**7 MARKETING AUTHORISATION HOLDER**

Norma Chemicals Ltd.  
51-53 Stert Street  
Abingdon  
Oxfordshire OX14 3JF  
United Kingdom

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

PL 0386/5005R

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

16 March 1990, 24 March 1996

**10 DATE OF REVISION OF THE TEXT**

20/04/2009