

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Smartans Antiseptic

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Active substance

Chlorhexidine gluconate 0.3g, Cetrimide 3.0g

Excipient also include Benzyl Benzoate

For the full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

A clear orange color liquid in a clear pet bottle in 125ml and 250ml

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

A topical antiseptic for prevention and management of infection or superficial skin trauma.

#### 4.2 Posology and method of administration

For Cutaneous use.

Two capfuls to ½ litre of warm water.

#### 4.3 Contraindications

Hypersensitivity to chlorhexidine, cetrimide or any of the excipients listed in section 6.1

#### 4.4 Special warnings and precautions for use

If symptoms persist or condition worsens or if a skin reaction occurs, discontinue use and consult a doctor.

For external use only.

Avoid contact with the eyes, ears, mouth or other mucosa.

If accidentally splashed into the eye, the open eye should be irrigated with water for at least 10 Minutes.

Smartans Antiseptic contains benzyl benzoate which may be mildly irritant to the skin, eyes and Mucous membranes.

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

No interaction studies have been performed with the topical forms.

#### 4.6 Fertility, pregnancy and lactation Pregnancy:

##### Pregnancy

There are no adequate data from the use of chlorhexidine and cetrimide in pregnant Women. The potential risk for humans is unknown but is most likely very low since chlorhexidine

and cetrimide are poorly absorbed following topical application (see section 5.2)

#### **Breast-feeding**

It is unknown whether Chlorhexidine gluconate and cetrimide are excreted in breast milk. There are no adequate data from the use of chlorhexidine and cetrimide in breast-feeding women. However, it is unlikely that the products are excreted in breast milk, since the products are poorly absorbed. After topical usage of the product, as a general precaution, rinse nipples thoroughly with water before breastfeeding

#### **Fertility:**

No data on human fertility are available.

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

Smartans antiseptic has no influence on the ability to drive and use machines.

### **4.8 Undesirable effects**

Within each system organ class, the adverse drug reactions are presented in order of decreasing seriousness. The frequency categories for each adverse drug reaction include: very common ( $\geq 1/10$ ); common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1,000$ ,  $< 1/100$ ); rare ( $\geq 1/10,000$ ,  $< 1/1,000$ ); very rare ( $< 1/10,000$ ); not known (cannot be estimated from the available data). The listed adverse events have estimated frequencies from post-marketing reporting.

#### **Immune system disorders:**

**Very rare:** Anaphylactic reaction, angioedema, urticaria

#### **Skin and subcutaneous tissue disorders:**

**Very rare:** Skin irritation

**Not known:** blistering

#### **Paediatric population:**

No investigations in children have been performed. However, frequency, type, and severity of adverse reaction in children are expected to be the same as in adults.

### **4.9 Overdose**

While accidental ingestion is unlikely to cause any systemic effects due to poor absorption of Chlorhexidine and cetrimide, Ingestion of high concentrations could cause irritation of the gastrointestinal mucosa/gastritis. Gastric lavage might be needed. Symptomatic treatment should be employed.

If swallowed, wash out mouth, drink plenty of milk or water and seek medical advice.

In case of overdose, seek medical attention or contact a poison control centre.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Chlorhexidine, combination – **Pharmacotherapeutic group:** Antiseptics and disinfectants.

**ATC Code:** D08AC52.

Chlorhexidine is an effective antiseptic with a wide range of activity against microorganisms, including gram positive and gram negative bacteria, fungi and viruses.

Cetrimide is a quaternary ammonium compound with surfactant and antiseptic properties.

## **5.2 Pharmacokinetic properties**

Chlorhexidine and cetrimide are poorly absorbed from the gastro-intestinal tract and skin.

## **5.3 Preclinical safety data**

There is minimal systemic absorption of chlorhexidine following topical administration. Preclinical data do not show genotoxic risk for chlorhexidine. Reproductive studies with chlorhexidine gluconate in animals have not revealed any teratogenic potential nor risk to the foetus. No additional information is available for cetrimide.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Isopropyl alcohol,  
Tween 80,  
Benzyl Benzoate,  
Tree oil,  
Eucalyptus oil,  
Lavender oil,  
Sodium Hydroxide,  
Sunset Yellow.

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

Three years.

## **6.4 Special precautions for storage**

Do not store above 30°C

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

PVC bottles with polypropylene screw caps.

Pack sizes: 125 ml, 250 ml.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

For external use only.

# **7 MARKETING AUTHORISATION HOLDER**

May & Baker Nigeria Plc.  
1, May & Baker Avenue,  
Off Idiroko Road,  
Ota, Ogun State.