

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Ster-Zac Powder

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hexachlorophane 0.33 % w/w.

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Cutaneous Powder

A fine, white, cutaneous powder.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

1. For the prevention of neonatal staphylococcal infections.
2. As an antiseptic for topical use on the skin.

##### 4.2 Posology and method of administration

1. **For the prevention of neonatal staphylococcal sepsis:**  
After ligation and cutting of the cord, apply a light dusting of the powder to the cord stump, surrounding skin, the perineum, groin and the axillae.  
After every napkin change, apply Ster-Zac Powder to the umbilicus cord, adjacent skin, perineum, groin, axillae.  
Continue the treatment until the cord stump drops away and the wound is healed.
2. **As an antiseptic:**  
Apply a light dusting of the powder to the affected area. Repeat daily.

##### 4.3 Contraindications

1. Hexachlorophane should not be applied to mucous membranes, large areas of skin or to burnt or damaged skin.
2. Hexachlorophane should not be applied under occlusive dressings.
3. Ster-Zac Powder is not recommended for use in pregnancy.

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

Do not use on badly burned or excoriated skin.

Hexachlorophane should be used with caution on infants, especially premature and low birth weight babies. In the prevention of neonatal staphylococcal infections, Ster-Zac Powder should only be administered to children under 2 years of age on medical advice.

For external use only.

Avoid contact with eyes, ears, mucous membranes, brain and meninges.

Keep out of reach of children.

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

Hexachlorophane activity can be reduced by contact with non-ionic surfactants.

#### **4.6 Pregnancy and lactation**

Not recommended for use in pregnant women.

No data available on effects on lactation.

Consult practitioner before use.

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

None stated.

#### **4.8 Undesirable effects**

Although rare, photosensitivity and skin sensitisation have occurred after repeated use. Central nervous system stimulation and convulsions have occurred after absorption of hexachlorophane from burnt or damaged skin.

#### **4.9 Overdose**

The Ster-Zac Powder formulation is unlikely to result in overdose.

If accidentally ingested, the patient should be treated symptomatically.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Hexachlorophane is a chlorinated bisphenol antiseptic with a bacteriostatic action against gram positive organisms. A 0.33% hexachlorophane dusting powder is used for the control of staphylococcal infections in the newborn.

#### **5.2 Pharmacokinetic properties**

No data available.

#### **5.3 Preclinical safety data**

None stated.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Talc

Maize starch

Zinc oxide

Perfume SN 24416

#### **6.2 Incompatibilities**

Hexachlorophane activity can be reduced by contact with non-ionic surfactants.

### **6.3 Shelf Life**

36 months.

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

Do not store above 25°C.

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

An internally lacquered tin plate container with a polyethylene closure with sprinkler holes.  
Size: 30g.

### **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**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

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## **8 MARKETING AUTHORISATION NUMBER**

PA 1175/13/1

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

Date of first authorisation: 25 February 1992

Date of last renewal: 25 February 2002

## **10 DATE OF REVISION OF THE TEXT**

February 2005