# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Cicatrin Cutaneous Powder.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of powder contains:

| | |
|---|---|
| Neomycin Sulphate | 3,300 units |
| Bacitracin Zinc | 250 units |
| Glycine | 10 mg |
| L (+) Cysteine | 2 mg |
| DL-Threonine | 1 mg |

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous powder.
A cream to white free-flowing powder.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Cicatrin Powder is broad-spectrum bactericidal preparations active against pathogens commonly found in infections of the skin. They are indicated in the prevention or treatment of superficial skin infection. These include:-

Prophylaxis in minor burns, cuts, scratches and abrasions and following the suturing of lacerations.

Treatment of superficial infected ulcers, cuts, scratches, and abrasions, superficial skin infections following surgical procedures, minor burns, impetigo and secondarily infected skin conditions.

The use of Cicatrin Powder does not exclude concomitant systemic therapy with other antibiotics where appropriate. (See *Special Warnings and Special Precautions for Use*).

### 4.2 Posology and method of administration

(Prophylaxis and treatment).

*Administration and dosage in adults:*
Before use, the area for application should be cleaned gently. Debris such as pus or crusts should be removed from the affected area.

A light dusting of powder should be applied once to four times daily, depending on the clinical condition. Treatment should not be continued for more than 7 days without medical supervision (see *Special Warnings and Special Precautions for Use*).

*Dosage in children:*
Cicatrin Powder is suitable for use in children (2 years and over) at the same dose as adults. A possibility of increased absorption exists in very young children, thus Cicatrin Powder is not recommended for use in neonates and infants (<2 years) (see *4.3 Contra-Indications* and *4.4 Special Warnings and Special Precautions for Use*).

*Dosage in the elderly:*
Cicatrin Powder is suitable for use in the elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur (see *4.2 Dosage in Renal Impairment* and *4.4 Special Warnings and Special Precautions for Use).*

*Dosage in patients with renal impairment:*
Dosage should be reduced in patients with reduced renal function (see *Special Warnings and Special Precautions for Use).*

## 4.3 Contraindications

The use of Cicatrin Powder is contra-indicated in patients who have demonstrated allergic hypersensitivity to any component of the preparation or to cross-sensitising substances such as framycetin, kanamycin, gentamycin and other related antibiotics.

The use of Cicatrin Powder is contra-indicated in patients hypersensitive to polymyxin B or neomycin.

The presence of pre-existing nerve deafness is a contra-indication to the use of Cicatrin Powder or any topical aminoglycoside in circumstances where significant systemic absorption could occur.

The use of Cicatrin Powder during pregnancy and lactation cannot be recommended in circumstances where significant systemic absorption of the active ingredients may occur (e.g. application to large areas of raw skin).

Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, the use of Cicatrin Powder in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

A possibility of increased absorption exists in very young children, therefore Cicatrin Powder is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature.

Cicatrin Powder should not be applied to the eyes.

## 4.4 Special warnings and precautions for use

Caution should be exercised so that the recommended dosage is not exceeded (see *Posology and Method of Administration and Contraindications*).

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity and both neomycin sulphate and bacitracin zinc have nephrotoxic potential.

In renal impairment the plasma clearance of neomycin is reduced (see *Dosage in renal impairment*).

As with other antibacterial preparations, prolonged use may result in overgrowth by nonsusceptible organisms, including fungi.

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

Following significant systemic absorption neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

## 4.6 Pregnancy and lactation

*Teratogenicity:*
There is insufficient information available to determine whether the active ingredients have teratogenic potential.

Neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal ototoxicity.

*Fertility:*
There is insufficient information available to determine whether any of the active ingredients can affect fertility.

*Pregnancy:*
There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation, therefore use of Cicatrin Powder is not recommended.

*Lactation:*
No information is available regarding the excretion of the active ingredient in human milk.

## 4.7 Effects on ability to drive and use machines

Not relevant.

## 4.8 Undesirable effects

The incidence of allergic hypersensitivity to neomycin sulphate in the general population is low. However, there is an increased incidence of sensitivity to neomycin in certain selected groups of patients in dermatological practice, particularly those with venous stasis eczema and ulceration.

Allergic hypersensitivity to neomycin following topical application may manifest itself as a reddening and scaling of the affected skin, as an eczematous exacerbation of the lesion, or as a failure of the lesion to heal.

Allergic hypersensitivity following topical application of bacitracin zinc has been reported but rare.

Anaphylactic reactions following the topical administration of bacitracin zinc have been reported but are rare.

## 4.9 Overdose

*Symptoms and signs:*

No specific acute symptoms or signs have been identified in association with excessive use of Cicatrin Powder. However, consideration should be given to significant systemic absorption *(see section 4.4, Special Warnings and Special Precautions for Use).*

*Management:*

Use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

Blood levels of neomycin sulphate and bacitracin zinc should also be determined and haemodialysis may reduce the serum level of neomycin sulphate.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

No data.

## 5.2 Pharmacokinetic properties

No data.

## 5.3 Preclinical safety data

*Mutagenicity:*
There is insufficient information available to determine whether the active ingredients have mutagenic potential.

*Carinogenicity:*
There is insufficient information available to determine whether the active ingredients have carcinogenic potential.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Maize starch

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

2 years.

## 6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.

## 6.5 Nature and contents of container

A polythene bottle with nozzle containing 15g or 50g of a cream to white free-flowing powder.

## 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

Cicatrin Powder should not be diluted.

# 7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
Stonemasons Way
Rathfarnham
Dublin 16.

## 8 MARKETING AUTHORISATION NUMBER

PA 1077/054/002

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

Date of first authorisation: 01 April 1977

Date of last renewal: 01 April 2007

## 10 DATE OF REVISION OF THE TEXT

November 2007