Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Noxyflex S Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains Noxytiolin 2.5g

3 PHARMACEUTICAL FORM

Powder for irrigation solution.
Fine white crystalline powder for reconstitution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical antibacterial and antifungal agent for use as an antiseptic for body surfaces, abscess cavities, urethra and bladder in the prophylaxis and treatment of superficial infection.

It may also be instilled into the peritoneal cavity in the presence of infective peritonitis, or into the pleural empyema cavity.

4.2 Posology and method of adminstration

Noxyflex-S is most commonly used at concentrations of 0.5% and 2.5% and is directly applied to the affected area twice daily or as required, as a wet dressing instillation or irrigation.

The solution should be pre-warmed to 37ºC prior to use.

Duration of treatment should not normally exceed 5 days.

4.3 Contraindications

Use by the intravenous route.

Use in patients with hypersensitivity to noxytiolin or to methylurea or formaldehyde.

4.4 Special warnings and precautions for use

The total daily usage in adults should not exceed 10 g of noxytiolin.

The product can be used concurrently with systemic antibiotics.

Intra-cavity instillation should be used only with caution in patients with blood dyscrasias, coagulation disorders or thyroid pathology.

4.5 Interaction with other medicinal products and other forms of interaction

Noxyflex S should not be mixed with other agents for topical administration.

4.6 Pregnancy and lactation

There is no experience of safety in use in pregnant patients. Noxyflex-S should not therefore be used during pregnancy. Application should avoid the breast area during lactation and breast-feeding.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Side effects include local discomfort and pain, and increased inflammation.

4.9 Overdose

The normal daily dosage should not exceed 10 g for continuous irrigation regimens. Fetid odour on the breath, preceding or following malaise, anorexia or nausea and/or vomiting are indicative of systemic absorption. Following immediate cessation of treatment symptoms normally disappear within 24 - 36 hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Noxytiolin has a wide spectrum of antifungal and antibacterial activity for the prevention and eradication of infection from the body surface and specified accessible cavities.

5.2 Pharmacokinetic properties

After intraperitoneal administration pharmacokinetic parameters were:

In rabbits:

$T\ ½^{(H)}$: Noxytiolin (N) - 0.61 ± 0.14; MT - 12.1 ± 3.43
C_{max} (µg/ml): 133.9 ± 81.2; MT 86.6 ± 12.7.

In humans:

$T\ ½^{(H)}$: N - 1.88 ± 0.72; MT - 15.92 ± 7.43
C_{max} (µg/ml): N = not determined; MR - 15.10 ± 8.17.

Absorption from the bladder with intact mucosae is negligible and blood levels cannot be detected.

N-methylthiourea is excreted as a urinary metabolite.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber that are additional to those already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf-life is two years. The reconstituted solution should be used within seven days.

6.4 Special precautions for storage

Do not store above 25^{o}C. The reconstituted solution should be stored at 2 to 8^{o}C.

6.5 Nature and contents of container

Amber glass, Type I Ph. Eur.vials (20 ml) with rubber stoppers and aluminium seals.

Supplied in boxes of 10 vials.

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

Solution preparation (20ml vial): The powder should be dissolved completely in a sufficient quantity of Water for Injections BP or Sodium Chloride intravenous infusion BP (0.9% w/v) by an aseptic technique. Slight difficulty may be experienced in preparing solutions.

To make a 2.5% solution: Add contents of one vial (2.5g) to 100m of Water for Injections BP or Sodium Chloride intravenous infusion BP and shake for a half to two minutes.

To make a 1% solution: Add contents of one vial (2.5g) to 250 ml of Water for Injections BP or Sodium Chloride intravenous infusion BP (0.9% w/v) and shake for a half to two minutes.

Containers of prepared solution are intended for single use only.

7 MARKETING AUTHORISATION HOLDER

Geistlich Sons Limited
Long Lane
Chester
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CH2 2PF
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8 MARKETING AUTHORISATION NUMBER

PA 143/11/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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