APPROVED PACKAGE INSERT

SCHEDULING STATUS:

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PROPRIETARY NAME (and dosage form):

BACTIGRAS Tulle gras dressing

COMPOSITION: (grams per 100 g)

A leno weave gauze, evenly impregnated with white soft paraffin B.P. containing 0,5 g chlorhexidine acetate B.P. per 100 g mass. The chlorhexidine acetate in Bactigras is micronised to facilitate release from the paraffin jelly and to ensure even dispersion therein.

PHARMACOLOGICAL CLASSIFICATION:

A 14.2 Wound Dressing

PHARMACOLOGICAL ACTION:

The dressing provides release of the medicament, chlorhexidine acetate, a broad spectrum antiseptic, and Bactigras is therefore designed to prevent wound colonisation by a wide range of Gram-positive and some Gram-negative organisms.

INDICATIONS:

(a) For topical use only.

(b) To reduce the incidence of infection in surgical, traumatic and ulcerative wounds and other skin conditions.

(c) For already infected wounds, the dressing can be used in conjunction with other topical and systemic antibacterial agents.

CONTRA-INDICATIONS:

Allergy to chlorhexidine acetate.

WARNINGS AND SPECIAL PRECAUTIONS:

Not to be used on more than 10 % of the body area.

Avoid contact with eyes, the middle ear, meninges and brain.

Incompatible with soaps, other anionic materials as well as potassium iodide. Use with oxidising wound cleaning agents should be avoided.

Bactigras is a single use product. If used on more than one patient, cross contamination,infection or loss of efficacy may occur. Opening the dressing pouch compromises the sterile barrier. Therefore any unused dressing should not be retained for later use.

INTERACTIONS:

None known.

PREGNANCY AND LACTATION:

The safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

The dressing is for administration to adults, children and infants; it may be changed daily but frequency of application will depend upon the clinical circumstances. It is intended that the dressingbe used principally on body wounds covering up to ten percent surface area. There is however no contra-indication for use on larger area wounds.

SIDE EFFECTS:

Chlorhexidine is well tolerated topically with minimal absorption. Sensitivity reaction is extremely rare.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known.

IDENTIFICATION:

A non-adherent tulle gras dressing. Each dressing is enclosed between two leaves of paper or plastic film, and is individually packed in a sealed peelable pouch.

PRESENTATION:

10 sterile dressings, 100 mm x 100 mm, in a carton.

10 sterile dressings, 100 mm x 400 mm, in a carton.

STORAGE INSTRUCTIONS:

Cartons should be stored flat in a cool place, not exceeding 25 ^{0}C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

J/14.2/31

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Smith & Nephew Pharmaceuticals (Pty) Ltd

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

December 7, 1999