APPROVED PACKAGE INSERT

SCHEDULING STATUS:

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PROPRIETARY NAME (and dosage form):

INTRASITE® GEL APPLIPAK®

COMPOSITION:

Each 15 g unit contains 0,345 g modified sodium carboxymethyl cellulose.

Each 25 g unit contains 0,575 g modified sodium carboxymethyl cellulose.

PHARMACOLOGICAL CLASSIFICATION:

A 14.2 Wound Dressing.

PHARMACOLOGICAL ACTION:

INTRASITE GEL APPLIPAK has no direct pharmacological action on the body as it is designed as a topical application for wound management. It acts by absorbing exudate from the wound surface, thereby preventing slough formation. The effective rehydrating action can produce rapid debridement of necrotic wounds and removal of slough without damaging fragile granulation tissue.

INDICATIONS:

INTRASITE GEL APPLIPAK is a dressing for cavity wounds, extravasation injuries, venous ulcers and decubitus ulcers (pressure sores).

CONTRA-INDICATIONS:

INTRASITE GEL APPLIPAK is for external use only and should not be taken by mouth. Hypersensitivity to any of the ingredients. Do not use on exposed muscle, tendon or bone. Do not use on deep partial thickness and full thickness burns.

WARNINGS AND SPECIAL PRECAUTIONS:

The initial application of INTRASITE GEL APPLIPAK should be under the direction of a health professional.

Wounds with signs of clinical infection, including fever and local symptoms such as tenderness, erythema or purulent discharge should be treated appropriately before using INTRASITE GEL APPLIPAK. A medical opinion should be sought before using INTRASITE GEL APPLIPAK on wounds at high risk of infection (e.g. diabetic ulcers, and ulcers caused by syphilis, tuberculosis and leprosy). Ulcers entirely or predominantly caused by arterial insufficiency (especially the feet) should regularly be inspected by a doctor. For external use only.

INTERACTIONS:

None Known.

PREGNANCY AND LACTATION:

The safety of this preparation in pregnancy and lactation has not been established

DOSAGE AND DIRECTIONS FOR USE:

1. Prepare the wound site by irrigating with a sterile solution e.g. saline.
2. Remove cap and swab the nozzle area of the pack with a suitable antiseptic swab.
3. Snap the patterned tip off the nozzle.
4. Keeping the nozzle tip clear of the wound surface, gently press the bowl of the pack

to dispense gel directly into the wound. Smooth over the surface of the wound, ensuring a minimum gel depth of 5 mm.

5. Cover the wound with a secondary dressing.

INTRASITE GEL APPLIPAK should be removed if leakage of exudate occurs through the secondary dressing. The frequency of dressing change depends on the condition of the wound and on the amount of exudate produced. A daily dressing change is recommended both for necrotic and sloughy wounds, but INTRASITE GEL APPLIPAK may be left for up to 3 days in later stages of healing.

SIDE EFFECTS :

Transitory discomfort and/or irritation have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT :

None Known.

IDENTIFICATION:

A colourless to white translucent premixed hydrogel absorption dressing, free from contaminants and particulate matter. Sterile until opened.

PRESENTATION:

Ten applipak units containing 15 g or 25 g of the gel in a carton.

STORAGE INSTRUCTIONS:

Store between 5 – 25 ^{0}C in a dry place. Keep away from sunlight.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

30/14.2/0117

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

Smith & Nephew Pharmaceuticals (Pty) Ltd

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