NOBAMED Paul Danz AG

NOBACUTIS®

REF 780107 (as of Lot 136942)

Product Description, Intended use, Application

Nonmedicated, sterile, individually packed, and disposable ointment swabs used as wound dressings, **size 7.5 cm x 7.5 cm**. The ointment swab consists of a binder-free carrier material, impregnated with vaselinum album (hydrophobic and not sensitizing). The swab's fibre lattice structure allows the unobstructed drainage of secretion, while keeping the wound moist and at the same time preventing the dressing from sticking to the wound. This allows an atraumatic change of dressing which reduces the pain for the patient.

Composition

Viscose, polyester, petrolatum (vaselinum album as per current edition of the Ph. Eur.)

Contra-Indications

If used on wounds without exudation the ointment swab may stick to the wound. NOBACUTIS® should not be used on deep and fissured wounds, wounds with cavities or pockets, undermined wounds, fistulas and abscesses. The swabs should not be placed on top of each other. A secondary absorbent cover is needed. NOBACUTIS® should not be used if there is a known hypersensitivity to the dressing or its ingredients.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical device according to MDD 93/42/EEC

The carrier material of the ointment swabs is tested in accordance with DIN EN 1644-1 and -2 for medical nonwoven swabs.

Sterilization of the product complies with DIN EN ISO 11137.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging:	PET-film
Secondary packaging:	aluminium-coated paper
Tertiary packaging:	folding box made of cellulose
Quaternary packaging:	carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN 1041

Storage and Transport

To be stored horizontally in a dry and dust-free environment, protected against direct sunlight, temperature must not exceed 25°C

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.