NOBAMED Paul Danz AG

RUDAVEN®-inject

REF 072486

Product Description, Intended Use Application

The sterile special plaster RUDAVEN®-inject of the size 9 cm x 6 cm consists of a white carrier non-woven with slit and hole punching, provided with an absorbent, non-adhesive wound pad made of non-woven, which serves to absorb blood and exudate from the puncture site. The special punching allows the dressing to fit securely at the puncture site so that the dressing closes without gaps. The plaster is provided with a hypoallergenic polyacrylate adhesive, which allows a secure fixation of the permanent vein cannula. An additional section of non-woven fabric is included as a cushion to relieve pressure on the cannula. The edges of the plaster are rounded to prevent rolling up. RUDAVEN®-inject is used not only for the secure fixation of permanent cannulas and catheters to the skin, but also for the sterile wound care of vascular puncture wounds by absorbing wound exudates and protecting the puncture wound from germ penetration and contamination by covering it. The disposable product is individually sterile packed.

Composition

Viscose, polyester, polyethylene, polyacrylic adhesive

Contra-Indications

Do not use on infected wounds. Not suitable for wounds that bleed or exude heavily

The product should not be used in the case of a known allergy against the material.

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, MDR (EU) 2017/745.*

Sterilization of the product complies with DIN EN 11135.

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

Packaging

Primary packaging:	paper-paper packaging
Secondary packaging:	folding box made of cellulose
Tertiary packaging:	carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

Storage and Transport

Dry and dustfree

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.