

NOBAMED Paul Danz AG

NOBAVARO[®]

REF 517807

Product Description, Intended use, Application

The carrier material of this zinc gel bandage $(8 \text{ cm } \times 7 \text{ m})$ consists of a lengthwise and crosswise bandage made of viscose and polyamide. This allows wrinkle-free application of the bandage even for less experienced persons. The product is used as a compression bandage for phlebological diseases. It is also used as a support and relief bandage, e.g. for sprains and for continued treatment after plaster casts. Sports injuries are also an application field due to their initially cooling properties.

Composition

Zinc oxide gel, bandage made of viscose and polyamide

Contraindications:

Zinc gel bandages may not be used with peripheric, arterial occlusions, decompensated cardiac insufficiency, septic phlebitis, phlegmasia coerulea dolens and on superinfected wounds.

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

Note

Zinc bandages do not replace a medically indicated additional thrombosis prophylaxis.

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

Packaging Primary:

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plastic film and aluminum

Secondary:

folding box made 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 ISO 20417.

Storage and transport:

Store in a horizontal position, do not store or transport at more than 35°C

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.

Product Data Sheet November 04, 2021 [Rev5], replaces: April 01, 2020 [Rev4]