



NOBAMED Paul Danz AG

RUDAPLAST®

REF 070395

Product Description, Intended use, Application

The fixing plaster (5.00 cm x 9.14 m) made of textile fabric on a roll with side disks is coated with a zinc oxide adhesive and therefore has a high adhesive strength. It is suitable for fixing wound dressings, bandages, tubes and catheters.

Composition

Viscose, zinc oxide adhesive (colophonium free)

Contraindications

The product should not be used on fragile skin, not on damaged skin and not in the case of a known allergy against the material.

Notes

To avoid swelling and circulatory disorders, fixation tapes are not applied on the extremities under tension in a circular way.

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 Legal Requirements

RUDAPLAST® is a medical product according to directive MDD 93/42/EEC and the regulation MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH. It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

Packaging

Primary packaging: folding box made of cellulose

Secondary 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 in a dry and dust-free environment, protected against sunlight.

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.