



## 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](http://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.