



RUDAPOR®

REF 070498

Product Description, Intended use,

Application

The hypoallergenic fixation tape, 7.5 cm x 9.14 m on a roll without side discs, is made of white paper covered with polyacrylate adhesive. RUDAPOR® is suited for the fixation of wound pads and bandage dressings.

Composition

Cellulose, polyester, polyacrylate adhesive

Contraindications

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

Residual risks, undesirable side effects, warnings

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

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

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 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

Dry and dustfree.

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.