

NOBAMED Paul Danz AG

RUDADERM®-universal

REF 090105

Product Description, Intended use, **Application**

The plaster stripes consist of a carrier material (1.6 x 5.7cm) which is made of a flexible, beige, waterproof synthetic and is coated with a hypoallergenic adhesive. The strips are individually packed and are used to cover injection sites, small punctures (for example vein punctions) and primary healing smaller injuries.

Composition

Polyethylene, vinyl acetat - carrier Viscose, polyester, polypropylene, polyethylene – wound pad, hypoallergenic adhesive

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: Secondary packaging: folding box

Teritary packaging:

Paper packaging

made of cellulose 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.

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.

Product Data Sheet: May 10, 2021 [Rev4], replaces: June 20, 2018 [Rev3]