



NOBAMED Paul Danz AG

RUDADERM[®]-universal

REF 090206

Product Description, Intended use, Application

The plaster stripes consist of a carrier material (1.9 x 7.6cm) 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: Paper packaging
Secondary packaging: folding box
made of cellulose
Tertiary 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.

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.