



NOBAMED Paul Danz AG

NOBACOLLOID®

REF 790110 (as of LOT 137289)

Product Description, Intended use, Application

NOBACOLLOID® (10 cm x 10 cm) is a hydrocolloid wound dressing.

The dressing consists of an absorbent hydrocolloid matrix and a breathable polyurethane film backing. A layer of wet gel forms once the hydrocolloid dressing gets in contact with the wound exudate, providing favourable conditions for the healing process. NOBACOLLOID® is indicated for the local treatment of leg ulcers and pressure ulcers.

Composition

Carboxymethyl cellulose matrix, pressure sensitive adhesive, polyurethane film

Contraindication

Do not use for infected wounds.
Do not use the product on any patients who may be allergic to any of its ingredients.

Precaution

The use of NOBACOLLOID® for leg ulcers does not replace the need for compression treatment (stockings or bandages) where prescribed.

The use of NOBACOLLOID® on pressure ulcers does not replace the need for normal nursing care.

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*.

Sterilization of the product complies with DIN EN 11137.

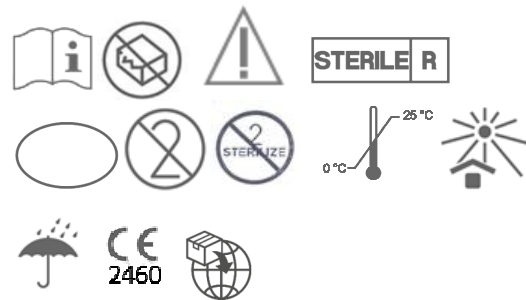
The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary:	foil-paper packaging
Secondary:	folding box made of cellulose
Tertiary:	carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417

Storage and Transport

Store NOBACOLLOID® flat.

Store with primary packing sealed.

Keep dry, keep away from sunlight.

NOBACOLLOID® should be stored in dry conditions at 0~25°C

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

In accordance with the requirements of the applicable local legislation and with the standards for the prevention of infections.