

NOBAMED Paul Danz AG

# **NOBACOLLOID**<sup>®</sup>

## REF 790115 (as of LOT 137289)

## Product Description, Intended use, Application

NOBACOLLOID<sup>®</sup> (15 cm x 15 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 <u>www.nobamed.com</u>



T 2460

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