



NOBAMED Paul Danz AG

NOBAALGIN®

REF 795110 (as of LOT 137029)

Product Description, Intended use, Application

Individually packed, sterile dressing, 10 cm x 10 cm, consisting of soft and highly absorbent alginate fibres. The non-woven structure of the dressing combined with its physical and chemical properties results in a high absorbency. As soon as NOBAALGIN® gets in touch with wound exudate, an ion exchange process takes place. The firm fibre is modified into a moist gel. This transformation assists in maintaining a moist wound environment. NOBAALGIN® is indicated for moderate to heavily exuding wounds. The gel can be removed atraumatically by means of forceps or glove-covered fingers.

Composition

Calcium alginate fibres and polysorbate

Contraindication

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

Precaution

Medical assessment of the condition of the wound and the causes of the delayed wound healing are necessary before treating wounds with impaired healing. Treatment with the product cannot replace treatment of the cause of the 795110he impaired healing. In the event of full thickness second degree and third degree burns, product may be used under medical supervision following debridement of necrotic tissue or surgical treatment.

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
Sterilization of the product complies with DIN EN 11137.

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

Packaging

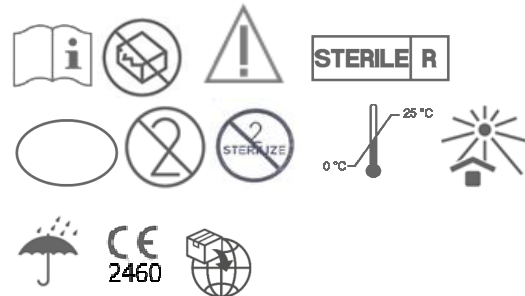
Primary packaging: foil-paper packaging

Secondary packaging: folding box made of cellulose

Tertiary packaging: 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

Keep dry, keep away from sunlight.
Alginate dressing 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.