

Cosmopor® Antibacterial



Spec.-No.: D 7.0407d

Department: PHSA-RD

Date: 12.09.2016

1. General Product Description

Cosmopor® Antibacterial is a sterile, self-adhesive wound dressing made of soft non-woven, coated with synthetic rubber based adhesive, with a highly absorbent pad, which includes the Dry Barrier Technology, which allows the exudates to penetrate to the wound but not be released from it, keeping the wound dry.

Inside the wound pad there is a layer coated with metallic silver which has an antibacterial activity including gram positive and gram negative bacteria.

The antibacterial activity is reduced to the internal part of the pad due to the effect of the Dry Barrier.

The pad is covered with a non-adherent net as wound contact layer.

The product is latex free.

Cosmopor® Antibacterial carries the CE mark according to EU directive 93/42/EEC for medical devices.

The product is classified as a Class I sterile medical device.

A conformity assessment has been performed for Cosmopor® Antibacterial and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of Cosmopor® Antibacterial, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Cosmopor® Antibacterial is intended to be used for cover post operational primary wounds with high level of exudation and a medium to high risk to be infected.

3. Presentations

Sterile, individually sealed.

| Type | Dimensions (cm) | Dimensions of wound pad (cm) |
|-------------------------|-----------------|------------------------------|
| Cosmopor® Antibacterial | 7,2 x 5 | 4 x 2,5 |
| Cosmopor® Antibacterial | 10 x 6 | 6,5 x 2,5 |
| Cosmopor® Antibacterial | 10 x 8 | 6,5 x 3,8 |
| Cosmopor® Antibacterial | 15 x 6 | 11 x 2,5 |
| Cosmopor® Antibacterial | 15 x 8 | 11 x 3,8 |
| Cosmopor® Antibacterial | 20 x 10 | 16 x 5,5 |

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4. Product Characteristics

Material composition:

| | | |
|---|-------------------|--|
| 1 | Backing material: | White, perforated spunlaced non-woven, 100% polyester |
| 2 | Adhesive: | Synthetic rubber-based adhesive, transparent, stripe coated |
| 3 | Wound pad: | The wound pad is composed by four layers: -Wound contact layer: permeable net made of polyethylene, which prevents the pad from sticking to the wound -Transmission layer: made of viscose which allows the exudate to be quick absorbed into the wound pad -Metallic silver coated layer with the antibacterial activity -Retention layer: containing super absorbent fibres (SAF) that retains the exudate |
| 4 | Silicone paper: | White silicone glassine paper |
| 5 | Sealing paper: | Printed paper, frame coated, cold and hot seal, latex free in combination with transparent polyethylene/polyester film |

5. Product Requirements

| | |
|---|---------------------------|
| Total weight (backing material + adhesive): | 68 ± 6,6 g/m ² |
| Adhesion on silk* | 12 ± 3 N/25mm |
| Wound pad absorption: | >800 % |
| Sterilization method: | EO |

*These values are only valid for the original coated roll


6. Labelling

Lot-No. with 9 digit code:

e.g.: X XXX XX XXX

| LOT | X | XXX | XX | XXX |
|-----|------|----------------------------|--------------------|----------------------------|
| | year | for internal purposes only | week of production | for internal purposes only |

Expiry date: 6-digit code:

e.g.  2015 06
year month

Shelf life: 5 years

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7. Packaging

Cosmopor® Antibacterial is sealed individually in peel pouches. Peel pouches are packed in folding boxes. Boxes are packed in transport carton acc. DIN, sealed with adhesive tapes, packed onto Euro pallet.

Date: 12.09.2016

A handwritten signature in blue ink, appearing to be "Dr. Irene Mijangos", written over a horizontal line.

Dr. Irene Mijangos
PHSA – RD
PAUL HARTMANN Spain