

Cosmopor® Advance



Spec.-No.: D 7.0407a

Department: PHSA-RD

Date: 12.09.2016

1. General Product Description

Cosmopor® Advance 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.

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

The product is latex free.

Cosmopor® Advance 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® Advance 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® Advance, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

Cosmopor® Advance is intended to be used as a self-adhesive sterile plaster for protection of post-surgical/primary wounds and for the absorption of exudate (especially wounds with a high exudate production). It can also be used for the protection of wounds following treatments such as disinfection, wound cleaning etc.

3. Presentations

Sterile, individually sealed.

Type	Dimensions (cm)	Dimensions of wound pad (cm)
Cosmopor® Advance	7,2 x 5	4 x 2,5
Cosmopor® Advance	10 x 6	6,5 x 2,5
Cosmopor® Advance	10 x 8	6,5 x 3,8
Cosmopor® Advance	15 x 6	11 x 2,5
Cosmopor® Advance	15 x 8	11 x 3,8
Cosmopor® Advance	20 x 10	16 x 5,5
Cosmopor® Advance	25 x 10	20,5 x 5,5
Cosmopor® Advance	35 x 10	30,5 x 5,5

Cosmopor® Advance



Spec.-No.: D 7.0407a
 Department: PHSA-RD
 Date: 12.09.2016

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 three 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 -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, 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
Wound pad absorption:	>800 %
Sterilization method:	EO


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

Cosmopor® Advance



Spec.-No.: D 7.0407a

Department: PHSA-RD

Date: 12.09.2016

7. Packaging

Cosmopor® Advance 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 read "Dr. Irene Mijangos".

Dr. Irene Mijangos
PHSA – RD
PAUL HARTMANN Spain