

SUPRASORB® X + PHMB

Antimicrobial HydroBalance wound dressing, sterile

REF 20540 – 20543

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1. Composition of the product

SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings and Packing Rope consist of:

- cellulose
- water
- polyhexamethylene biguanide
- polyester film (backing sheets on both sides of the wound dressings)

This product data sheet covers the following items:

REF	Product description	Size	Pcs/ SC
20540	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	2 x 2 in.	5
121908	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	2 x 2 in.	4
20451	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	3.5 x 3.5 in.	5
121909	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	3.5 x 3.5 in.	4
20542	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	5.5 x 8 in.	5
20543	Suprasorb® X + PHMB Antimicrobial HydroBalance Packing Rope	0.75 x 8.5 in.	5

2. Packaging, structure and composition

2.1 Unit container

- peel pouch consisting of polyester, polyethylene, and aluminium

2.2 Shelf container

- folding box (cellulose)
- instructions for use (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings and Packing Rope are produced according to specification in hygienic conditions, packed as described in their relevant packaging specification. The product is sterilized by gamma irradiation in compliance with DIN EN ISO 11137, part 1-3.

4. Description

White to off-white, smooth antimicrobial dressings or rope, respectively, which are effective against a large spectrum of pathogens. The antimicrobial wound dressings are covered on both sides with a polyester film. They are available in various sizes.

5. Properties (see valid instructions for use)

SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings and Rope exert an antimicrobial action against a wide spectrum of pathogens. Additionally, depending on the condition of the wound, the products can either donate moisture to the wound or absorb excess exudate. This creates a moist wound environment.

The material makes it easy to conform to the wound's particular shape and depth. The products are therefore especially suitable for areas of the body which are difficult to dress.

The positive properties of the dressing counter possible adhesion to the wound or to the secondary dressing. The moist environment with a cooling effect is perceived by patients as pleasant and pain-relieving.

SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings and Rope are for single use only and must not be resterilized.

6. Intended purpose (see valid instructions for use)

SUPRASORB® X+ PHMB Antimicrobial HydroBalance Wound Dressings / Rope may be used for management of wounds-at-risk or infected wounds which show light to moderate exudation, or are superficial or partial to full thickness wounds (application examples see section "Indications" in the Instructions for use).

7. Medical device classification

SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings or Rope respectively are medical devices of Class III in terms of Rule 13. (Council Directive 93/42/EEC concerning medical devices, Annex IX)

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of SUPRASORB® X+ PHMB Antimicrobial HydroBalance Wound Dressings and Rope are safe when the products are used appropriately and for the intended purpose.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical devices SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings and Rope and that they are designed, manufactured and packaged in such a way that they will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately – at temperatures between +5°C and +30°C - SUPRASORB® X + PHMB Antimicrobial HydroBalance Wound Dressings and Rope have a shelf life of 3 years provided the original package remains unopened and undamaged.

10. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.
Packaging materials must also be disposed of in compliance with applicable national requirements.

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signed by
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