

SUPRASORB® X HydroBalance - Wound Dressings, sterile

REF 20531 - 20534

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1. Composition of the product

SUPRASORB® X HydroBalance Wound Dressings consist of:

- cellulose
- water
- polyester film (backing sheets on both sides of the wound dressing)

the primary product is soaked in 0.085 % chlorhexidine gulconate. Which is used as a preservative prior to gamma sterilization.

This product data sheet covers the following items:

REF	Product description	Size
20534	Suprasorb® X HydroBalance Wound Dressing, sterile	5 x 5 cm
20531	Suprasorb® X HydroBalance Wound Dressing, sterile	9 x 9 cm
20532	Suprasorb® X HydroBalance Wound Dressing, sterile	14 x 20 cm
20533	Suprasorb® X HydroBalance Packing Rope, sterile	2 x 21 cm

2. Packaging, structure and composition

2.1.1 Unit container

- peel pouch consisting of polyester, polyethylene and aluminum

2.2 Shelf container

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

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

SUPRASORB® X HydroBalance Wound Dressings are produced according to specification in hygienic conditions and individually sealed, into a peel pouch, then packed for transport.

The products are sterilized by gamma rays according to DIN EN ISO 11137 part 1 - 3.

4. Description

White to off-white smooth dressing and rope respectively. The wound dressings are covered on both sides with a polyester film. They are available in various sizes.

5. Properties (see also valid instructions for use)

Depending on the wound condition, SUPRASORB® X HydroBalance Wound Dressings / Rope can either provide the wound with moisture or absorb excess exudate. The product creates a moist wound environment. (Dressing change is atraumatic). The material can simply be adjusted to the wound shape and depth. The products are suitable for parts of the body which are difficult to dress. There is minimal adhesion to the wound or to the secondary dressing. The moist environment by the product has a cooling effect that may reduce pain.

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

6. Intended purpose (see also valid instructions for use)

SUPRASORB® X HydroBalance Wound Dressings and Rope may be used for the management of wounds which show light to moderate exudation, or are superficial or partial to full thickness wounds (application examples see section "indication" in the instructions for use).

7. Medical device classification

The SUPRASORB® X HydroBalance Wound Dressings are medical devices of Class IIb in terms of Rule 4.
(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 HydroBalance Wound Dressings are safe when the product is 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 HydroBalance Wound Dressings 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 HydroBalance wound dressings 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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