

SUPRASORB® P non-adhesive PU foam dressing, non-adhesive, sterile

REF 20405 – 20409

REF 31264, 31265, 31311

REF 121904, 121905, 123464, 123466

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1. Composition of the product

The SUPRASORB® P non-adhesive PU foam dressing consists of:

- polyurethane foam layer, white
- polyurethane film (support layer), skin-colored
- perforated polyurethane film (wound contact layer), transparent
- hot-melt adhesive netting made from copolyamide
- polyacrylate adhesive

This product data sheet covers the following items:

| International | Regional | Product | Size |
|---------------|------------|--|----------------|
| REF 20405 | REF 31311 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 5 x 5 cm |
| REF 20406 | REF 121904 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 7.5 x 7.5 cm |
| REF 20407 | REF 121905 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 10 x 10 cm |
| ----- | REF 123464 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 10 x 12 cm |
| ----- | REF 123465 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 12.5 x 12.5 cm |
| REF 20408 | REF 31264 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 15 x 15 cm |
| REF 20409 | REF 31265 | Suprasorb® P non-adhesive PU-foam dressing, non-adhesive, sterile | 15 x 20 cm |

----- REF 123466 Suprasorb® P non-adhesive 20 x 20 cm
PU-foam dressing, non-adhesive, sterile

2. Packaging, structure, and composition

2.1 Unit Container

- four-edge sealed pouch consisting of cellulose and polyethylene

2.2 Shelf Container

- cellulose folding box
- instructions for use, made from cellulose, white

2.3 Transit Container

- corrugated cardboard box made from cellulose

3. Manufacture

The SUPRASORB® P non-adhesive PU foam dressing is manufactured to specification under hygienic conditions and packaged as described in its respective packaging specifications.

The device is sterilized with ethylene oxide in compliance with DIN EN ISO 11135-1.

4. Description

The SUPRASORB® P non-adhesive PU foam dressing consists of a skin-coloured polyurethane film (support layer), a white polyurethane foam layer and a perforated, transparent polyurethane film (wound contact layer). Support layer and foam layer are bonded by means of a copolyamid glue netting, foam layer and wound contact layer by means of a polyacrylate adhesive.

5. Properties

Flexible, water vapor permeable foam dressing with rounded corners.

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

The SUPRASORB® P non-adhesive PU foam dressing can be used for the treatment of all wounds provided that they are moderately exuding and superficial e.g. ulcers or bedsores.

7. Medical device classification

The SUPRASORB® P non-adhesive PU foam dressing is a medical device of Class IIb in terms of Rule 4.

(Council Directive 93/42/EEG concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of SUPRASORB® P non-adhesive PU foam dressing are safe if the product is used for the purposes intended.

The purpose of this documentation and the statements made herein is to show that there is no risk involved in the use of the product SUPRASORB® P non-adhesive PU foam dressing and that it is designed, manufactured, and packaged in such a way that it 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 not exceeding 25°C), the foam dressings have a shelf life of 3 years.

10. Disposal

The user is advised to observe current national legislation, norms, and guidelines regulating the disposal of medical waste.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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Signed by

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