

# Suprasorb® H

## Hydrocolloid Wound Dressing thin, sterile

REF 20410 - 20414, 20424

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Update: S. Golz

### 1. Composition of the product

Suprasorb® H Hydrocolloid wound dressing, thin, consists of:

- backing: polyurethane
- hydrocolloid layer: carboxymethylcellulose  
styrene-isoprene-styrene-copolymer  
resins, mineral oil, antioxidants
- protector: paper, siliconized on one side

This product data sheet covers the following items:

International:

REF	Product description	Size	UC/ SC / TC
20424	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	5 x 5 cm 2 in. x 2 in.	1 / 10 / 1650
20410	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	5 x 10 cm 2 in. x 4 in.	1 / 10 / 480
20411	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	5 x 20 cm 2 in. x 8 in.	1 / 10 / 250
20412	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	10 x 10 cm 4 in. x 4 in.	1 / 10 / 720
20413	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	15 x 15 cm 6 in. x 6 in.	1 / 5 / 50
20414	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	20 x 20 cm 8 in. x 8 in.	1 / 5 / 50

Regional:

REF	Bezeichnung	Größe	UC/ SC / TC
121910	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	5 x 10 cm 2 in. x 4 in.	1 / 8 / 384
121911	Suprasorb® H thin, Hydrocolloid Wound Dressing, thin, sterile	10 x 10 cm 4 in. x 4 in.	1 / 8 / 576

**2. Packaging, structure and composition****2.1 Unit container**

- peel pouch consisting of polyester and polyethylene
- as well as polyester, polyethylene and cellulose in the case of REF 20424

**2.2 Shelf container**

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

**2.3 Transit container**

- corrugated cardboard box (cellulose)

**3. Manufacture**

Suprasorb® H Hydrocolloid Wound Dressings, thin, are produced according to specification in hygienic conditions and packed as described in the relevant packaging specification.

The product is sterilized with radiation in compliance with DE EN ISO 11137 part 1-3.

**4. Description**

Suprasorb® H Hydrocolloid Wound Dressing, thin, consists of a backing, a hydrocolloid layer, as well as a cover.

The product is available in various sizes

**5. Properties**

Suprasorb® H Hydrocolloid Wound Dressing, thin, is a self-adhesive wound dressing with a semipermeable backing.

The dressing is intended for single use only and must not be re-sterilized.

The product is sterile unless the package has been opened or damaged

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

Suprasorb® H Hydrocolloid wound dressing, thin, can be used for the treatment of the following wounds: pressure sores, arterial ulcers, venous lower leg ulcers, diabetic ulcers, skin donor sites if they have light exudation and are superficial.

**7. Medical device classification**

Suprasorb® H Hydrocolloid wound dressing, thin, is a medical device of Class IIa 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 material used in the manufacture of Suprasorb® H Hydrocolloid wound dressing, thin, is safe when the products are used appropriately and for the purposes intended.

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® H Hydrocolloid 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 not exceeding 25°C – Suprasorb® H Hydrocolloid wound dressing, thin, has a shelf life of 5 years.

**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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Quality & Regulatory Affairs