

Suprasorb® P sensitive Silicone Foam Dressing

REF 140160-140161, 139061-139062, 139068-139069, 140162,
139070, 139080, 140163, 139081, 139083, 139086-139088
140164-140165, 139350-139456, 139355-139357, 139556,
142075-142077

March 2021

1. Composition of the form of application (product)

Suprasorb® P sensitive Silicone Foam Dressing consists of:

Suprasorb® P sensitive border/heel, sacrum, multisite:

Suprasorb® P sensitive Silicone Foam Dressing consists of a silicone wound contact layer, a absorbent PU foam, a nonwoven layer, a super-absorbent core and a protective backing.

Suprasorb® P sensitive border lite/multisite:

Suprasorb® P sensitive Silicone Foam Dressing consists of a silicone wound contact layer, a absorbent PU foam, a non-woven layer and a protective backing.

Suprasorb® P sensitive non-border:

Suprasorb® P sensitive Silicone Foam Dressing consists of a silicone wound contact layer, a absorbent PU foam and a protective backing.

The product data sheet is valid for the following items:

International products:

REF	Product name	Size
140160*	Suprasorb® P sensitive border	5 x 5 cm
140161*	Suprasorb® P sensitive border	7.5 x 7.5 cm
139061	Suprasorb® P sensitive border	10 x 10 cm
139062**	Suprasorb® P sensitive border	12.5 x 12.5 cm
139068**	Suprasorb® P sensitive border	7.5 x 8.5 cm
139069	Suprasorb® P sensitive border	15 x 15 cm

140162*	Suprasorb® P sensitive border	15 x 20 cm
139070**	Suprasorb® P sensitive border	20 x 20 cm
139080	Suprasorb® P sensitive border lite	5 x 5 cm
140163*	Suprasorb® P sensitive border lite	7.5 x 7.5 cm
139081**	Suprasorb® P sensitive border lite	5 x 10 cm
139083	Suprasorb® P sensitive border lite	10 x 10 cm
139086**	Suprasorb® P sensitive border lite	7.5 x 8.5 cm
139087**	Suprasorb® P sensitive border lite	9 x 15 cm
139088**	Suprasorb® P sensitive border lite	10 x 20 cm
140164*	Suprasorb® P sensitive border lite	15 x 15 cm
140165*	Suprasorb® P sensitive border lite	15 x 20 cm
139350	Suprasorb® P sensitive non-border	5 x 5 cm
139351	Suprasorb® P sensitive non-border	10 x 10 cm
139352**	Suprasorb® P sensitive non-border	10 x 20 cm
139353	Suprasorb® P sensitive non-border	15 x 15 cm
139354**	Suprasorb® P sensitive non-border	20 x 20 cm
139455	Suprasorb® P sensitive non-border	7.5 x 7.5 cm
139456	Suprasorb® P sensitive non-border	15 x 20 cm
139355	Suprasorb® P sensitive sacrum	17 x 17.5 cm
139356	Suprasorb® P sensitive heel	23.5 x 25 cm
139357	Suprasorb® P sensitive multisite	12 x 15 cm
139556**	Suprasorb® P sensitive sacrum	23 x 23 cm
142075	Suprasorb® P sensitive multisite border	7,5 x 9,5 cm
142076	Suprasorb® P sensitive multisite border	16 x 20 cm
142077	Suprasorb® P sensitive multisite border lite	7,5 x 9,5 cm

* only available in Germany

** not available in Germany

2. Packaging, structure and composition

2.1 Basic package/Unit Container

1 Unit = 1 four-edge sealed pouch
made of polyester, polyethylene and cellulose

2.2 Commercial packaging/Shelf Container

10 Units = 1 folding box consisting of cellulose,
1 instructions for use made of cellulose

2.3 Shipping package/Transit Container

1 corrugated cardboard box, made of cellulose:

REF	Pcs.	Folding boxes
140162, 139070, 140165, 139351, 139353, 139354, 139456, 139355, 139356, 139357, 139556	100	10
139069, 139088, 140164, 139352, 139455	150	15
140161, 139061, 139062, 139068, 140163, 139081, 139083, 139086, 139087, 142076	200	20
140160, 139080, 139350	240	24
142075, 142077	300	30

3. Production

The information about production is the responsibility of the legal manufacturer (Huizhou Foryou Medical Devices Co., Ltd.).

4. Description

Suprasorb® P sensitive Silicone Foam Dressing consists of a wound contact layer, a absorbent PU foam, a non-woven layer (border, border lite, heel, sacrum, multisite) and a protective backing.

The product variants border, heel, sacrum and multisite also have a super-absorbent core.

5. Properties

The triple-, four- or five-layer construction facilitates dynamic fluid management to provide an optimal moist wound environment, which promotes faster wound closure and may help to reduce the risk of maceration. The gentle silicone layer can be lifted and repositioned without losing its adherence. The layer can also minimise pain to the patient as well as trauma to wounds and the surrounding skin during dressing changes. The absorbent pad layer provides superior absorption and locks exudate in.

Indications:

- pressure ulcers
- leg and foot ulcers
- traumatic wounds
- surgical wounds
- donor sites
- abrasions
- burns (1st and 2nd degree)

6. Intended purpose/use

Suprasorb® P sensitive Silicone Foam Dressing may be used to treat all wounds, provided they are

- moderately to heavily exuding (border, heel, sacrum, multisite)
- moderately exuding (non-border)
- slightly to moderately exuding (border lite)
- superficial to
- deep* wounds

The dressing can also be used on dry/necrotic wounds in combination with gels.

*For deep wounds, apply a wound dressing according to the instructions for use of the respective dressing, if necessary.

7. Medical device classification

Suprasorb® P sensitive Silicone Foam Dressing is a Class IIb medical device according to Rule 4. (Medical Device Directive 93/42/EEC, Annex IX)

8. Biological assessment and compatibility

The information about biological assessment and compatibility is the responsibility of the legal manufacturer (Huizhou Foryou Medical Devices Co., Ltd.)

9. Shelf life

When stored correctly (in a cool and dry place, protected from direct sunlight at a temperature of 5°C to 40°C), the shelf life is 3 years.

10. Disposal

The user has to observe the applicable national laws, standards and guidelines for the disposal of waste from the medical sector.

National requirements also have to be taken into account when disposing of packaging materials.

11. Legal manufacturer:

The following legal manufacturer hereby confirms the accuracy of the information provided in this product data sheet:

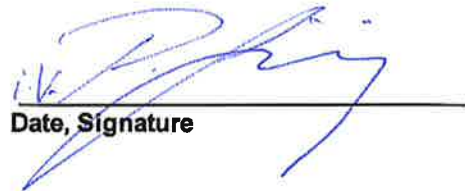
Legal manufacturer:

Huizhou Foryou Medical Devices Co., Ltd.
No.1 Shangxia North Road
Dongjiang Hi-tech
Industrial Park
516005, Huizhou
P.R. China

Distributor:

Lohmann & Rauscher GmbH & Co. KG
Westerwalstraße 4
56579 Rengsdorf
Germany

李 苏 金 22 March, 2021
Date, Signature


Date, Signature

EC-REP:

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20537 Hamburg/Germany