# SUPRASORB® G
# Amorphous Gel, sterile

# REF 20478 - 20479

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## 1. Composition of the product

SUPRASORB® G Amorphous Gel consists of:

- water
- propylene glycol
- sodium carboxymethyl cellulose
- sodium citrate buffer

The complete product SUPRASORB® G amorphous gel (including the packaging) does not contain diethyl-hexyl phthalates in a quantity > 0.1%.

This product data sheet covers the following items:

| | | |
|---|---|---|
| REF 20478 | SUPRASORB® G Amorphous Gel | syringe with 6 g, sterile |
| REF 20479 | SUPRASORB® G Amorphous Gel | syringe with 20 g, sterile |

## 2. Packaging, structure and composition

### 2.1 Unit container

Syringe:
- piston rod and cylinder made of polypropylene
- cap and stopper made of chlorbutyl rubber

Blister pack of polyvinyl chloride and cellulose

### 2.2 Shelf container

- cellulose folding box
- instructions for use (cellulose)

### 2.3 Transit container

- corrugated cardboard box (cellulose)

## 3. Manufacture

SUPRASORB® G Amorphous Gel is produced according to specification in hygienic conditions, packed as described in its relevant packaging specification and sterilized.
The gel is sterilized by steam in compliance with DIN EN ISO 17665-1.
The syringes packed into the blisters are sterilized by ethylene oxide in compliance with DIN EN ISO 11135-1.
The gel is filled into sterile syringes under aseptic conditions according to DIN EN ISO 13408.

## 4. Description

SUPRASORB® G Amorphous Gel is a transparent hydrogel consisting of CMC polymers, propylene glycol and water. It is presented in single-use, sterile 6-g or 20-g syringes. The product is individually packed and sterile.

## 5. Properties (see valid instructions for use)

SUPRASORB® G Amorphous Gel is a transparent, high viscous hydrogel with a high water content which is able to absorb moisture as well as donate moisture.
SUPRASORB® G Amorphous Gel is intended for single use only and must not be re-sterilized.
The product is sterile unless the packaging is opened or damaged.

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

SUPRASORB® G Amorphous Gel is intended to be used for the desloughing of necrotic and fibrinous tissue, particularly in deep wounds.

## 7. Medical device classification

SUPRASORB® G Amorphous Gel is a medical device 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® G Amorphous Gel are safe if the product is 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 device SUPRASORB® G Amorphous Gel 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 - SUPRASORB® G Amorphous Gel has 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 refuse.
Packaging materials must also be disposed of in compliance with applicable national requirements.

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