

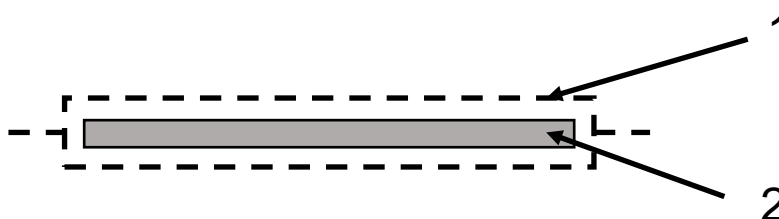
Product Data Sheet

1.0 Name of the product	Cutimed® Sorbion® Sachet S & Variants
2.0 Product description	
2.1 Description	<p>a) Super-absorbent dressing</p> <p>b) Cutimed® Sorbion® Sachet is a sterile, hydroactive, gel-forming strongly exudate-absorbing wound dressing. The dressing consists of a strongly water-retaining superabsorbent core and an outer layer from a hypoallergenic polypropylene. Both sides of the dressing can be applied to the wound. The product does not contain any pharmacologically active substances and is free of binders or adhesives.</p>
2.2 Intended purpose	<p>Cutimed® Sorbion® Sachet is intended for the treatment of exuding wounds with moderate to excessive levels such as decubitus, ulcus cruris, diabetic foot ulcers and other wounds healing through secondary intention, oozing laparotomy wounds, fistulas to the skin, exulcerating carcinomas, postoperative wound dehiscence and similar exuding wounds.</p> <p>Note: Cutimed® Sorbion® Sachet S Drainage, due to its specific shape, was developed for use with catheters, drainages, etc.</p>
2.3 Instructions for use	yes
2.4 Warnings and precautions for use	<p>Do not use if the pouch is already open or damaged as the sterility of the dressing is guaranteed only when the pouch is unopened and undamaged prior to use.</p> <p>Cutimed® Sorbion® Sachet is for single use only. Re-use may lead to increased risk of infection or cross contamination. Do not re-sterilize.</p> <p>Cutimed® Sorbion® Sachet should be used under medical supervision.</p> <p>Please always follow the instructions of any product that is used in combination.</p> <p>Do not cut the dressing. It must remain intact and uncut.</p> <p>Before applying Cutimed® Sorbion® Sachet, make sure that the wound has sufficient amount of exudate. Avoid contact with the following areas: mucous membranes (risk of drying and adhesion) and eye area.</p> <p>If the treated condition deteriorates, fails to improve or if a side effect is observed, consult a physician or an appropriate health care professional.</p> <p>A temporary increase in wound size may occur at the start of a normal healing process; consult a medical professional to determine the cause of any significant change in wound size, color, or odor.</p> <p>Cutimed® Sorbion® Sachet should not be used in combination with therapies involving increased heat development or in which high-energy radiation (UV, γ- or x-ray) is used, since this can compromise the mechanical integrity of the product.</p>
2.5 Contraindications	There are no known contraindications.
2.6 Transport Precautions	Dry, clean and without exposure to direct sunlight.

2.7 Duration of application

Cutimed® Sorbion® Sachet can remain in place for up to 7 days, depending on wound conditions and saturation of wound dressing. It is recommended to change the dressing every 24 hours initially, moving to less frequent changes as necessary. A completely soaked dressing must always be avoided.

2.8 Composition



	Designation (incl. no. in drawing)	Description	% of final product
<i>Cutimed Sorbion Sachet S</i>			
1	Sachet	Polypropylene nonwoven	14,5
2	Inner Core	Superabsorber and Cellulose tissue	85,5
<i>Cutimed Sorbion Sachet Extra</i>			
1	Sachet	Polypropylene nonwoven	12,5
2	Inner Core	Superabsorber and Cellulose tissue	87,5
<i>Cutimed Sorbion Sachet Multistar</i>			
1	Sachet	Polypropylene nonwoven	13,3
2	Inner Core	Superabsorber and Cellulose tissue	86,7
<i>Cutimed Sorbion Sachet XL</i>			
1	Sachet	Polypropylene nonwoven	9,3
2	Inner Core	Superabsorber and Cellulose tissue	90,7
<i>Cutimed Sorbion Sachet Drainage</i>			
1	Sachet	Polypropylene nonwoven	19,3
2	Inner Core	Superabsorber and Cellulose tissue	80,7

2.9 Product range

Size	Per folding box	Per shipper	Product code
Cutimed® Sorbion® Sachet S			
7,5 cm x 7,5 cm	10	62	73232-00
7,5 cm x 7,5 cm	25	34	73232-01
7,5 cm x 7,5 cm	50	33	73232-02
5 cm x 12 cm	10	34	73232-03
5 cm x 12 cm	25	23	73232-04
5 cm x 12 cm	50	10	73232-05
10 cm x 10 cm	10	62	73232-06
10 cm x 10 cm	25	34	73232-07
10 cm x 10 cm	50	18	73232-08
10 cm x 20 cm	10	34	73232-09
10 cm x 20 cm	25	23	73232-10
10 cm x 20 cm	50	10	73232-11
15 cm x 15 cm	10	36	73232-12
15 cm x 15 cm	25	14	73232-13
15 cm x 15 cm	50	6	73232-14
20 cm x 20 cm	10	22	73232-15
20 cm x 20 cm	25	12	73232-16
20 cm x 20 cm	50	6	73232-17
20 cm x 30 cm	10	17	73232-18
20 cm x 30 cm	25	10	73232-19
20 cm x 30 cm	50	6	73232-20
10 cm x 18 cm	25	23	73232-21
10 cm x 18 cm	50	10	73232-22
7,5 cm x 7,5 cm	12	62	73232-40
7,5 cm x 7,5 cm	24	34	73232-41
7,5 cm x 7,5 cm	48	33	73232-42
5 cm x 12 cm	12	34	73232-43
10 cm x 10 cm	12	62	73232-44
10 cm x 10 cm	24	34	73232-45
10 cm x 10 cm	48	18	73232-46
10 cm x 20 cm	12	34	73232-47
10 cm x 20 cm	24	23	73232-48
10 cm x 20 cm	48	10	73232-49
15 cm x 15 cm	12	36	73232-50
15 cm x 15 cm	24	14	73232-51
20 cm x 20 cm	12	22	73232-52
20 cm x 20 cm	24	12	73232-53
20 cm x 20 cm	48	6	73232-54
20 cm x 30 cm	12	17	73232-55
20 cm x 30 cm	24	10	73232-56
20 cm x 30 cm	48	6	73232-57
7,5 cm x 7,5 cm	10	62	73232-58
5 cm x 12 cm	10	34	73232-59
10 cm x 10 cm	10	62	73232-60
10 cm x 20 cm	10	34	73232-61
15 cm x 15 cm	10	36	73232-62
20 cm x 20 cm	10	22	73232-63
20 cm x 30 cm	10	17	73232-64
10 cm x 10 cm	3	30	73232-65
10 cm x 20 cm	3	16	73232-66
20 cm x 20 cm	3	10	73232-67

2.9 Product range	Size			Per folding box	Per shipper	Product code	
	Cutimed® Sorbion® Sachet Extra						
	5 cm x 5 cm			5	62	73234-00	
	7,5 cm x 7,5 cm			5	62	73234-01	
	10 cm x 10 cm			5	36	73234-02	
	10 cm x 20 cm			5	34	73234-03	
	20 cm x 20 cm			5	20	73234-04	
	20 cm x 30 cm			5	10	73234-05	
	Cutimed® Sorbion® Sachet Multi Star						
	8 cm			5	62	73237-00	
	8 cm			10	62	73237-01	
	14 cm			5	36	73237-02	
	14 cm			10	36	73237-03	
	8 cm			10	62	73237-06	
	14 cm			10	36	73237-07	
	8 cm			3	30	73237-08	
	Cutimed® Sorbion® Sachet XL						
	25 cm x 45 cm			10	7	73240-00	
	25 cm x 45 cm			5	12	73240-01	
	25 cm x 45 cm			12	7	73240-03	
	25 cm x 45 cm			6	12	73240-04	
	25 cm x 45 cm			10	7	73240-05	
	25 cm x 45 cm			2	9	73240-06	
	Cutimed® Sorbion® Sachet S Drainage						
	10 cm x 10 cm			10	62	73241-00	
	10 cm x 10 cm			25	34	73241-01	
	10 cm x 10 cm			50	18	73241-02	
10 cm x 10 cm			3	30	73241-04		
10 cm x 10 cm			10	62	73241-05		
2.10 Storage conditions	Store dressing away from direct sunlight at ambient temperature and humidity.						
2.11 Shelf life/ Storage time	3 years						
2.12 Sterilization	EO-sterilization according to ISO 11135.						
2.13 Reimbursement Information	Product is reimbursable in most countries. For more information please reach out to your Essity contact or contact the market access department directly.						
2.14 Key quality parameters	Characteristic	Method	Target				
	Absorption by free swelling	DIN EN 13726-1	200 ± 100 g /100 cm ²				

3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

3.1 Components

Raw materials used in product formulation

Substance	Included in formulation
Natural rubber Latex	No
Lanolin and its derivatives	No
Colophony	No
Colophony derivatives	No
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Partly in folding box and shipper case

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch BSN medical GmbH cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change																				
1 / January 2023	All	Set up of new document																				
2 / January 2023	2.9	Addition of product codes: <table border="1"><tr><td>73232-21</td></tr><tr><td>73232-22</td></tr><tr><td>73232-44</td></tr><tr><td>73232-45</td></tr><tr><td>73232-46</td></tr><tr><td>73232-47</td></tr><tr><td>73232-48</td></tr><tr><td>73232-49</td></tr><tr><td>73232-59</td></tr><tr><td>73232-60</td></tr><tr><td>73232-61</td></tr><tr><td>73232-62</td></tr><tr><td>73232-65</td></tr><tr><td>73232-66</td></tr><tr><td>73232-67</td></tr><tr><td>73237-06</td></tr><tr><td>73237-07</td></tr><tr><td>73237-08</td></tr><tr><td>73240-05</td></tr><tr><td>73240-06</td></tr></table>	73232-21	73232-22	73232-44	73232-45	73232-46	73232-47	73232-48	73232-49	73232-59	73232-60	73232-61	73232-62	73232-65	73232-66	73232-67	73237-06	73237-07	73237-08	73240-05	73240-06
73232-21																						
73232-22																						
73232-44																						
73232-45																						
73232-46																						
73232-47																						
73232-48																						
73232-49																						
73232-59																						
73232-60																						
73232-61																						
73232-62																						
73232-65																						
73232-66																						
73232-67																						
73237-06																						
73237-07																						
73237-08																						
73240-05																						
73240-06																						