Aquacel[™]Ag

Foam



PRODUCT DESCRIPTION:

Aquacel[™] Ag Foam dressings are sterile Hydrofiber[™] foam wound dressings, consisting of a waterproof outer polyurethane film, a polyurethane foam layer and, a Hydrofiber[™] wound contact layer (Sodium carboxymethylcellulose with 1.2% ionic Silver), bound together with an adhesive melt layer. The adhesive version has a silicone adhesive border.

The polyurethane foam and Hydrofiber™ materials within the pad absorb wound fluid and bacteria. The Hydrofiber™ wound contact layer absorbs wound exudate from the wound. This causes it to swell and conform to the wound bed, leaving less space for bacteria to grow. The 1.2 % ionic silver in the dressing kills pathogenic microorganisms, including wound bacteria, yeasts and moulds. The Hydrofiber™ wound contact layer also supports a moist wound-healing environment and aids autolytic debridement. The silicone border provides skin-friendly adhesion and supports atraumatic removal

Aquacel[™] Ag Foam dressings have a polyurethane film backing which provides a breathable, waterproof, viral and bacterial barrier, which protects the wound from external contaminants, reducing the risk of infection. This outer film layer acts as a barrier to the wound against bacterial and bloodborne viral pathogens.



Dressing Size cm	Max wound size	CVT number	pieces/ package
Aquacel [™] Ag Foam Non-adhesive			
5x5		420639	10
10x10		420642	10
15x15		420645	5
15x20		420806	5
20x20		420646	5
Aquacel™ Ag Foam Adhesive			
8x8	3 x 3 cm	420805	10
10x10	5 x 5 cm	420681	10
12,5x12,5	6,5 x 6,5 cm	420627	10
17,5x17,5	11,5 x 11,5 cm	420628	10
21x21	15 x 15 cm	420629	5
25x30	19 x 24 cm	420807	5
Heel 19,8x14	12 x 7 cm	420647	5
Sacrum 20x16,9	11,5 x 9,5 cm	420648	5

The dressing may be cut; if cut, additional tape or film dressing should be used to create a seal and ensure a bacterial barrier.



CLINICAL BENEFITS:¹

Aquacel[™] Ag Foam absorbs wound fluid and bacteria, providing a moist wound healing environment, aiding autolytic debridement and removing dead-space between the wound and dressing interface.

Aquacel[™] Ag Foam is designed to manage excess exudate levels which may further damage the wound bed and surrounding skin.

Aquacel[™] Ag Foam provides a physical microbial, viral, and waterproof barrier to protect the wound. Aquacel[™] Ag Foam effectively kills bacteria, yeasts and moulds

INTENDED USE:

AquacelTM Ag Foam dressings have been designed to be used as a primary dressing. AquacelTM Ag Foam dressings may be used with the direction of a healthcare professional, for the management of exuding acute and chronic wounds which are at risk of infection or show signs of infection.

INTENDED USER:

AquacelTM Ag Foam dressings are to be used by Health Care Professionals, carers and patients who are under the direction of a Health Care Professional.

DIRECTIONS FOR USE

Always check instructions for use please see IFU in product box before clinical use



ADDITIONAL INFORMATION		
Can be used with compression therapy ^{*,2}	YES	
Help facilitate easy removal	YES	
MRI safe	YES	
Exudate levels	Aquacel [™] Ag Foam is designed to manage excess exudate levels which may further damage the wound bed and surrounding skin.	

*Use of additional products and therapies should be undertaken with the direction of a Health Care Professional.

INDICATIONS FOR USE:

Aquacel[™] Ag Foam dressings are indicated for:

- wounds where there is an infection or an increased risk of infection
- leg ulcers
- venous stasis ulcers
- leg ulcers of mixed aetiology
- arterial ulcers
- pressure ulcers
- diabetic foot ulcers
- surgical wounds
- partial thickness burns
- traumatic wounds

INTENDED PATIENT POPULATION:

AquacelTM Ag Foam is designed to be used on patients with one of the wound types listed in the Indications that show signs of, or are at risk of infection.

DURATION OF USE

Aquacel[™] Ag Foam dressings can be worn for up to 7 days, dressings should be changed earlier if clinically indicated.

The requirement for Aquacel[™] Ag Foam should be re-assessed after 14 days and alternative wound management considered where appropriate.



CONTRAINDICATIONS

Aquacel^{TM} Ag Foam dressings should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or any of its components.

Aquacel[™] Ag Foam dressings are not compatible with oxidising agents such as hydrogen peroxide or hypochlorite solutions.

CTEDILIZATION:	
STERILIZATION:	
Sterile	YES
Method	Sterilized using ethylene oxide
CERTIFICATIONS:	
CE mark	CE 2797
MDR 2017/745	Class III
MATERIAL SPECIFICATIONS:	
List of ingredients	Polyurethane film, Polyamide binding layer, Polyurethane foam, Hydrofiber wound contact layer (containing 1.2% w/w silver) Silicone trilaminate (adhesive only)
STORAGE AND HANDLING:	
Before Use	Keep away from sunlight
	Keep dry.
	Store at room temperature (10°C - 25°C/50°F - 77°F).
After use	After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local state and federal laws and regulations.

References:

1. Aquacel TM Ag Foam IFU Revised: 10-2022 1727205V1 2. Clinical Evaluation Report: RPT-005750 Title: Aquacel Ag Foam_DHF 704_CER (2022) Convatec Data on file

Convatec Limited

First Avenue. Deeside Industrial Park Deeside, Flintshire CH5 2NU, UK



UNOMEDICAL A/S Aaholmvej 1-3, Osted 4320 LEJRE DENMARK



Convatec Denmark A/S

CVR 31477093, Transformervej 14, 1., 2860 Søborg, Denmark Tlf.: +45 48 16 74 74 www.convatec.dk

Convatec Norway AS

Org. nummer: MVA 992 780 118 Visiting address: Nils Hansens Vei 8, 0667 Oslo Postadresse: Postboks 6464 Etterstad, 0605 Oslo Tlf.: +47 21 09 67 90 www.convatec.no

Convatec (Sweden) AB

Organisationsnummer: 556754-8473, Box 3096, 16973 Solna, Sweden Visiting address: Gustav III:s Boulevard 42, plan 9, 16973 Solna, Sweden Tlf.: +46 020-21 22 22 ww.convatec.se

Convatec Oy

Y-tunnus 1644589-9, Aviapolis, Karhumäentie 3, 01530 VANTAA, Finland P: +358 020 7659 600 www.convatec.fi



For full description and instructions for use please see IFU in product box The information in this document is subject to change without notice. (C) 2023 ConvaTec. ® /TM indicate trademarks of the ConvaTec group of companies AP-66793-NOR-ENG-v1