

# ASKINA® CALGITROL® Ag

## TECHNICAL FILE



### ADMINISTRATIVE INFORMATION

HEAD OFFICE ADDRESS	B. Braun Hospicare Ltd. Colloney, Co. Sligo. Ireland
SBA & PRODUCT MANAGER	Wound Management, Louis vanden Schrieck
SAFETY OFFICER MEDICAL DEVICES	Stephan Krause
LAST UPDATE	02/09/2020

### DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE

COMMON NAME (FAMILY)	Silver Dressings (563)
TRADE NAME	Askina® Calgitrol® Ag
REFERENCES	6211003, 6211010, 6211503, 6211510,6212010
GMDN CODE	48124 - Exudate-absorbent dressing, non-gel, antimicrobial
MEDICAL CLASS	III

### DESCRIPTION OF THE DEVICE

Askina® Calgitrol® Ag is a sterile dressing consisting of two layers: an absorbent polyurethane foam layer which provides for the absorption of wound exudate, and an ionic silver alginate matrix which provides for broad antimicrobial effectiveness and helps prevent contamination from external bacteria. In the presence of wound exudate, the silver alginate matrix helps maintain a moist wound environment conducive to natural healing conditions. The individual single peel pack is designated as a microbiological barrier to assure the sterility of the product.

### COMPOSITION OF THE DEVICE

#### Components

Polyurethane Hydrophilic Foam
Ionic Silver Alginate Matrix

PROPERTIES OF THE DEVICE	Absorbency	Absorbency 5 x 5cm sample > 14 g
	pH	9±1
	Silver content (Ag)	96-222 mg/100cm <sup>2</sup>
	Zone of inhibition	> 2mm
	MVT	> 3000g/m <sup>2</sup> /24hrs

## KEY DRIVERS & INDICATIONS

KEY DRIVERS	Prevention of infection
	Management of infected or critically colonized wounds
	Askina® Calgitrol® Ag has broad spectrum antimicrobial qualities
	Askina® Calgitrol® Ag is entirely non-toxic for the body
	Reduces pain
	Inhibits bacterial cell division which eliminates the development of resistance
	Creates an optimal moist environment to promote wound healing
	Non-staining, non-irritating
Free from animal tissue and bovine derivatives	

INDICATIONS	Askina® Calgitrol® Ag is indicated for the management of:
	Partial to full thickness wounds, stage I – IV pressure ulcers
	Venous leg ulcers
	Second degree burns
	Donor sites
Askina® Calgitrol® Ag is indicated for external use only and may be used in the management of infected wounds under medical supervision at the discretion of the physician.	

## STERILIZATION PROCESS: REPORT

STERILE MD: YES/NO	Yes
STERILIZATION METHOD	Gamma irradiation

## CONSERVATION AND STORAGE CONDITIONS

STORAGE CONDITIONS	[5° - 25°] C
TRANSPORT CONDITIONS	No restrictions
SHELF LIFE	3 years from date of manufacture

## SAFETY IN USE

TECHNICAL: MRI, X-RAY DETECTABLE	N/A
ORGANIC	Latex, DEHP, phthalate free
BIOCOMPATIBILITY	Doc References n° HOSP 450, HOSP 451, HOSP 452, HOSP 461

## STANDARDS & REQUIREMENTS

Council Directive 93/42/EEC  
UNE-EN ISO 13485:2018  
UNE-EN ISO 14971:2012  
UNE EN ISO 14698-1: 2004  
UNE-EN ISO 14644-2:2016  
UNE-EN ISO 1041:2009+A1:2014  
UNE-EN ISO 15223-1:2016  
UNE-EN ISO 10993-1:2018  
MEDDEV 2.7.1. Rev.4  
ICH Guideline Q1A (R2)  
European Pharmacopeia

## RECOMMENDED USE

Yes, presence of IFU n°P820-1067 Revision 04.

## IFU: YES/NO PRECAUTION OF USE CONTRAINDICATION

Precaution: In the event of clinical infection, topical silver does not replace the need for systemic therapy or other adequate infection treatment. This medical device contains 4.81mg of propylene glycol per cm<sup>2</sup> of dressing, which is equivalent to 0.069 mg/kg body weight/cm<sup>2</sup>. Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

Contraindications: Askina® Calgitrol® Ag should not be used on patients with a known sensitivity to alginates or silver neither where the presence of metals is contraindicated. Askina® Calgitrol® Ag is contraindicated for ulcers resulting from certain infections or medical conditions, such as: Tuberculosis, syphilis, deep fungal infection, third degree burns. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

## ADDITIONAL PRODUCT INFORMATION

### REUSABLE/SINGLE USE DEVICE

Single patient use.

Re-use of single-use devices creates a potential risk to the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

## PACKAGING & REFERENCES

Transport box for dispatching and additional protection against damage during transportation.



### PACKAGING & PRODUCT LABEL



### REFERENCES

Reference	Description	Size	Quantity per box
6211003	Askina® Calgitrol® Ag	10 x 10 cm	3
6211010	Askina® Calgitrol® Ag	10 x 10 cm	10
6211503	Askina® Calgitrol® Ag	10 x 15 cm	3
6211510	Askina® Calgitrol® Ag	15 x 15 cm	10
6212010	Askina® Calgitrol® Ag	20 x 20 cm	10

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