

ASKINA® CALGITROL® THIN

TECHNICAL FILE



ADMINISTRATIVE INFORMATION

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SAFETY OFFICER MEDICAL DEVICES	Stephan Krause
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DESCRIPTION, COMPOSITION AND PROPERTIES OF THE DEVICE

COMMON NAME (FAMILY)	Silver Dressings (563)
TRADE NAME	Askina® Calgitrol® THIN
REFERENCES	6201010, 6201510, 6202005, 6202010, 6202110, 6202403, 6204003, 6205510
GMDN CODE	48124 - Exudate-absorbent dressing, non-gel, antimicrobial
MEDICAL CLASS	III

DESCRIPTION OF THE DEVICE

Askina® Calgitrol® THIN is a sterile dressing consisting of an ionic silver alginate matrix which provides a release of ionic silver for broad antimicrobial effectiveness and helps prevent contamination from external bacteria. In the presence of wound exudate, the silver alginate matrix gels, to form a moist wound environment conducive to natural healing conditions. Its metallized medical packaging film with excellent UV, oxygen and moisture barrier properties provide consistent and easy open peel strength. The individual single peel pack is designated as a microbiological barrier to assure the sterility of the product.

COMPOSITION OF THE DEVICE

Components

Polyethylene liner
Ionic Silver Alginate Matrix

PROPERTIES OF THE DEVICE	Silver content	96 - 222 mg/100 cm ²
	Zone of inhibition	> 2mm
	pH	9 ± 1
	MVT	> 3000g/m ² /24hrs

KEY DRIVERS & INDICATIONS

KEY DRIVERS	Prevention of infection
	Management of infected or critically colonized wounds
	Management of omphalocele
	Askina® Calgitrol® THIN has broad spectrum antimicrobial qualities
	Askina® Calgitrol® THIN 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® THIN 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® THIN 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. Keep out of heat and humidity
TRANSPORT CONDITIONS	Keep out of heat and humidity
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 456, HOSP 457, HOSP 458, HOSP 463

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°P820-1271 Revision 01.

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 cm² of dressing, which is equivalent to 0.069 mg/kg body weight/cm². 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® THIN should not be used on patients with a known sensitivity to alginates or silver. Askina® Calgitrol® THIN should not be used where the presence of metals is contraindicated. Askina® Calgitrol® THIN is contraindicated for ulcers resulting from infection, such as tuberculosis, syphilis, or deep fungal infection, and for third degree burns. Askina® Calgitrol® THIN does not absorb wound exudate

ADDITIONAL PRODUCT INFORMATION

REUSABLE/SINGLE USE DEVICE

Single use.

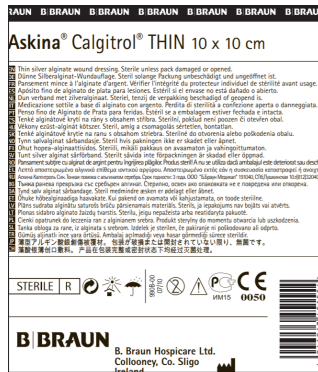
Re-use of single-use devices creates a potential risk to the patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

PACKAGING & REFERENCES

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



PACKAGING & PRODUCT LABEL



REFERENCES

Reference	Description	Size	Quantity per box
6201010	Askina® Calgitrol® THIN	10 x 10 cm	10
6201510	Askina® Calgitrol® THIN	15 x 15 cm	10
6202005	Askina® Calgitrol® THIN	20 x 20 cm	5
6202010	Askina® Calgitrol® THIN	20 x 20 cm	10
6202110	Askina® Calgitrol® THIN	10 x 20 cm	10
6202403	Askina® Calgitrol® THIN	20 x 40 cm	3
6204003	Askina® Calgitrol® THIN	40 x 40 cm	3
6205510	Askina® Calgitrol® THIN	5 x 5 cm	10

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