Askina® Calgitrol® Paste

Product Data Sheet

Administrative information	
Legal Manufacturer	B. Braun Avitum Italy S.p.A., Via XXV Luglio, 11, 41037 Mirandola (MO), Italy.
Product Management	Wound Management
Last Update	09/08/2024

Description, composition and properties of the device	
Trade Name	Askina® Calgitrol® Paste
Reference	7211598; 7211599
Medical Class	Class III (MDR)
Description of the device	Askina® Calgitrol® Paste is a sterile, primary wound dressing consisting of an ionic silver alginate matrix in paste form, which provides antimicrobial barrier 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. Askina® Calgitrol® Paste is a conformable dressing that allows intimate contact with the wound surface. It is supplied sterile in a 15 g tube. The tube has a cannula to aid application of the paste into tunnels, sinuses, and all deep wounds.
Composition of the device	Askina® Calgitrol® Paste contains purified water, glycerin, alginate, propylene glycol, calcium gluconate, borax, ionic silver, pectin, and maltodextrin.

Key drivers & Indications	
Key drivers	• Sterile primary wound dressing with an added ancillary antimicrobial activity. • Used for management of infected wounds or wounds at high risk of infection. • It helps maintain a moist wound environment conducive to natural healing conditions. • The high conformability allows a close contact to the wound bed. • Broad antimicrobial effectiveness. • Immediate availability of silver ions. • Sustained controlled release of silver to the wound bed during use of the dressing.
Intended Use	Askina® Calgitrol® Paste is intended to be used as a sterile primary wound dressing with an added ancillary antimicrobial activity, to manage moist environment in infected wounds or wounds at high risk of infection. - For external use only. - Before application, the wound bed should be free of residuals of other products to avoid reduced effectiveness and/or incompatibilities causing injury, severe harm and death to the patient.
Indications	Askina® Calgitrol® Paste is indicated for the management of partial to full-thickness wounds infected or at high risk of infection, such as e.g., pressure ulcers, vascular ulcers, diabetic foot ulcers, surgical incisions, wound dehiscence, trauma wounds, second degree burns, donor sites, skin tears, cavity wounds, tunneling wounds, sinus tracts. The responsible physician must assess the wound for signs and symptoms of infection or risk of infection. Askina® Calgitrol® Paste is to be used under medical supervision and close monitoring by the responsible health care professional. If there is an underlying condition that impairs healing, Askina® Calgitrol® Paste alone may not be sufficient and must be combined with appropriate treatment of the underlying condition.
Contraindications	Askina® Calgitrol® Paste is contraindicated in: • Patients with known hypersensitivity to any of the components in the dressing. • Procedures where the presence of ionic silver may interfere or are contraindicated. • Wounds being treated with enzymatic debridement. • Wounds resulting from certain infections or medical conditions, such as: – Tuberculosis, – Syphilis, – Deep fungal infection, – Third degree burns, – Active vasculitis, – Heavily bleeding wounds. • Pregnant and breast-feeding women. • Children. • Infants. • Neonates. The responsible physician or other healthcare professional could define further contraindications based on wound characteristics and patient condition, according to state-of-the-art medical knowledge.

IFU: Yes/No	Yes
Reusable/single use device	Multiple use, single patient device

Sterilization process	
Sterile: Yes/No	Yes
Sterilization method	Sterilization is performed in the final packaging by gamma irradiation

Conservation and storage conditions	
Storage conditions	Store between 5-25 °C.
Shelf life	24 months

Safety in use	
Technical: MRI, X-ray detectable	For patients undergoing MRI (Magnetic Resonance Imaging), Askina® Calgitrol® Paste must be removed from the area within the anatomical field being imaged. If Askina® Calgitrol® Paste is being used on any area not within the image field, it may remain in place during the MRI.
Biocompatibility	Biocompatibility studies showed the device has no indication of eliciting the following responses: – Cytotoxicity, – Intracutaneous Irritation, – Acute Systemic Toxicity, – Sub-Acute Toxicity and Implantation (combined study), – Sensitization.

Standards & requirements	
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 13726-1	Test methods for primary wound dressings – Part 1: Aspects of absorbency
EN ISO 11137	Sterilization of health care products - Radiation
EN ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 13485	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971	Medical Devices – Application of risk management to medical devices

Packaging & references

Reference	Description	Size	Box Quantity
7211598	Askina Calgitrol Paste	15 g	5
7211599	Askina Calgitrol Paste	15 g	10

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