Evaluation of a new silver foam dressing in patients with critically colonised venous leg ulcers

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The enclosed peer-reviewed journal article is provided in the interest of free exchange of truthful scientific information. The barrier functions of the **Restore**® Foam Dressing with Silver* may help reduce infection in moderately to high exuding partial- and full-thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor and graft sites. Restore wound care dressings are intended for single use.

In this article, the authors note that the foam dressing was left in place for an average of 2.66 ±1.93 days (range 1-13). The interval between dressing changes beyond three to four days is not recommended by Hollister Wound Care LLC, and has not been cleared by the FDA.

Warnings and Precautions: Do not re-use the dressing. Store the dressing flat and at room temperature.

Contraindications: Restore Foam Dressing Silver, Non-Adhesive with TRIACT Technology should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or one of its components.

- * The product cited in this article – UrgoCell® Silver (Laboratoires URGO, Dijon, France) – is marketed in the U.S. by Hollister Wound Care LLC as **Restore**® Foam Dressing Silver, Non-Adhesive with TRIACT™ Technology. (In the United States, lipidocolloid technology is known as TRIACT Technology.)
- This device is restricted to sale by or on the order of a physician or licensed healthcare professional.
- The Instructions for Use (IFU) is attached. The full IFU – written in English, French and Spanish – is available at: **www.hollisterwoundcare.com/products/ifus.html**

Evaluation of a new silver foam dressing in patients with critically colonised venous leg ulcers

• **Objective:** To evaluate the performance (efficacy and safety) of an absorbent dressing impregnated with silver salts (UrgoCell Silver) in the management of leg ulcers with clinical signs of critical colonisation.

• **Method:** This was a prospective multicentre non-comparative phase III clinical trial. Patients were assessed weekly for up to four weeks. Assessment included clinical assessment of critical colonisation (severe spontaneous pain between dressing changes, erythema, oedema, malodour and heavy exudate), wound area tracing and photography. Acceptability was documented by the nursing staff when dressings were changed between two weekly evaluations.

• **Results:** Forty-five leg ulcers were included. At baseline the mean number of clinical signs of critical colonisation per ulcer was 3.6 ± 0.7, which decreased to 1.2 ± 1.2 at the end of the fourth week of follow-up (an average reduction of 2.3 ± 1.3, $p<0.001$). Oedema, malodour, erythema and spontaneous pain disappeared at the fourth week in 80%, 70%, 69% and 65% of the treated ulcers respectively. Compared with baseline, the mean reduction in ulcer area was 35.0 ± 58.0% (median 33%, $p<0.001$) after the four weeks treatment. Granulation tissue covered a mean 77% of the ulcer surface area at four weeks, compared with 41% at baseline. Only three local events were documented: contact dermatitis, a burning sensation and erythema.

• **Conclusion:** The results suggest that the test dressing had a favourable influence on the wound prognosis, and was well tolerated and accepted in the treatment of venous leg ulcers with clinical signs of critical colonisation.

• **Declaration of interest:** This study was sponsored by Laboratoires Urgo, Chenôve, France.

silver dressing; critical colonisation; venous leg ulcers

Recognising and managing chronic wounds at risk of developing infection is subject to intense debate.[1] There are difficulties in diagnosing infection,[2] with some studies supporting the concept of critical colonisation as an intermediate stage between simple colonisation and frank infection.[3-6]

Nevertheless, critical colonisation has yet to be clearly characterised.[7,8]

At this stage, antiseptic agents for critical colonisation may control bacterial load and prevent the development of infection,[9,10] although they may be toxic to fibroblasts and other viable cells.[11,12] However, silver appears to have only a very weak toxic potential and only occasionally to induce microbial resistance,[13-16] while *in vitro* studies have demonstrated the effectiveness of silver-based dressings against pathogenic bacteria.[17,18] Thus, use of silver-releasing dressings with appropriate debridement on wounds at risk of developing infection is beneficial.[9,19,20]

The purpose of this non-comparative study was to evaluate the efficacy and safety of a silver foam dressing (UrgoCell Silver, Laboratoires Urgo, Chenôve, France) in the management of venous leg ulcers with clinical signs of critical colonisation.

Method

Patients

This was an open non-randomised multicentre study involving 12 sites including dermatology and vascular medicine hospital wards, private physicians, angiologists and dermatologists. It was conducted in adult outpatients treated for a venous leg ulcer or a leg ulcer of predominantly venous origin. Mixed ulcers were included if a venous aetiology was predominant.

Physicians selected critically colonised ulcers for inclusion. Ulcers were considered to be critically colonised if at least three of the five following signs were present:

- Severe spontaneous pain between two dressing changes
- Perilesional erythema
- Local oedema
- Malodour
- Heavy exudation.

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Table 1. Baseline patient and leg ulcer characteristics

Patient characteristics (n=45)	
Sex (M/F)	30/15 (67%/33%)
Age (years)	74.8 ± 11.2 (48–92)
Body weight (kg)	80.8 ± 20.3 (47–127)
Patient history and associated diseases*	
High blood pressure	31 (69%)
Heart disease	15 (33%)
Diabetes	10 (22%)
Cigarette smokers	10 (22%)
History of allergy	5 (11%)
Other history	16 (36%)
Venous history*	
Venous thrombosis	19 (42%)
Superficial venous surgery	15 (33%)
Sclerotherapy	20 (44%)
Family history of venous disease	34 (76%)
Target ulcer characteristics	
Leg ulcer duration	15.2 ± 18.5 (1–96)
Recurrent leg ulcer	24 (53%)
Surface area (cm^2)	12.6 ± 10.0 (2.6–48)
Altered perilesional skin	39 (87%)
ABPI	0.95 ± 0.12 (0.70–1.20)
Wound aspect (% of wound surface)	
Sloughy tissue	58.3 ± 29.4 (10–100) Median: 60
Granulation tissue	41.3 ± 29.4 (0–90) Median : 0
Necrotic tissue	0.4 ± 1.8 (0–10) Median : 40

* More than one pathology may be present
ABPI = ankle brachial pressure index
Results are presented as either numbers and percentages, or as mean ± standard deviation with the range in brackets

Selection of these signs was based on a EWMA position document[8] and our own clinical experience.

Additional inclusion criteria were:

- Ulcer area between 5cm^2 and 40cm^2
- Ulcer duration between three and 24 months
- Ankle brachial pressure index greater than 0.7
- Ability to wear compression therapy and the test dressing.

The main exclusion criteria were:

- Patients receiving systemic antibiotics at the time of enrolment or in the previous week
- Patients who had had deep venous thrombosis in the three previous months
- Ulcers with clinical signs of infection or erysipelas of the lower limb such as cellulitis, green exudate and inflammation of the surrounding skin and that required systemic antibiotics, according to the investigating physician.

Method

Efficacy — the primary study endpoint — was judged by the physician at each weekly visit based on an assessment of each of the five selected signs of critical colonisation. The dressing was considered effective if there was a significant reduction in these signs and in the wound surface area.

Secondary endpoints — tolerance (occurrence of local adverse events) and acceptability of the dressing — were also assessed.

At baseline, after gaining the patients' written consent to participate, the patient's general characteristics were recorded, the test leg ulcer was fully described, wound-area tracing and photography were performed, and the dressing was applied.

Participants were seen weekly for four weeks by the investigating physician. Full study documentation and recommendations for dressing use were provided, along with a nurse case-report form to document the dressing-change characteristics at each dressing removal.

The nurse in charge of the patient performed dressing changes in the patient's home between the weekly clinical evaluations. Wounds were cleansed with normal saline only. The frequency of dressing change was at the investigating physician's discretion, based on the state of the wound.

All study participants were offered compression therapy in combination with the test dressing.

The test dressing

UrgoCell Silver is composed of three layers:

- A lipidocolloid dressing (Urgotul) impregnated with silver salts (contact)
- A highly absorbent polyurethane foam (intermediate)
- A polyurethane film (outer).

This silver dressing is indicated for moderately to highly exudating chronic wounds that are at high

risk of clinical infection. The manufacturer recommends that the dressing be changed every two to three days.[21-24]

Statistical analysis

Data analyses were performed with the SAS 9.0 for Windows. A descriptive statistical analysis was performed on all patients included in the trial. The statistical analysis was performed on the basis of intention-to-treat (ITT) for all endpoints, and all patients who received at least one care operation with the test dressing after their inclusion were included in the efficacy and tolerance analyses. No patients were withdrawn before the first week of treatment. If a patient withdrew before the end of the treatment period, the analysis took account of the last evaluation (last observation carried forward, LOCF).

Continuous data were described by sample size, mean, standard deviation, median and range.

The following statistical methods were used for changes with respect to inclusion:

- MacNemar test for binary variables
- Signed ranks test (Wilcoxon) for the clinical score
- Student's paired t-test for continuous variables.

Ethics

The study protocol was approved by the Medical Ethics Committee of Versailles (France), and the clinical trial was then conducted in compliance with good clinical practice and the principles of the Declaration of Helsinki.

All patients gave written consent to participate after having received full written information about the study objectives and conduct.

Results

Baseline characteristics: patients and leg ulcers

Forty-five patients were included in the study between February and September 2005 by the 12 investigating centres. Table 1 outlines the baseline patient and ulcer characteristics. Perilesional skin was documented as 'healthy' in only six of the 45 patients (13%).

Table 2 outlines the clinical indicators of critical colonisation, as defined for the purposes of this study, and the number of patients who demonstrated one or more of them at baseline. All ulcers had at least three clinical signs at baseline, and 44% (n=20) had four to five signs.

Study participants had previously been treated by the investigating physicians. Treatments had included paraffin gauze, foam or alginate. At baseline, 73% (n=32) of the study ulcers were considered to be stagnant or deteriorating.

Forty-one patients (91%) had received compression before inclusion in the study: 62% monolayer bandaging, 22% multilayer bandaging and 16% compression hosiery.

Table 2. Clinical indicators of critical colonisation and clinical score

Clinical indicators	Baseline No. of patients (%)	Week 4 No. of patients (%)
Pain between two dressing changes	31 (69)	11 (24)
Perilesional erythema	38 (84)	12 (27)
Oedema	24 (53)	5 (11)
Malodour	28 (62)	8 (18)
Heavy exudate	40 (89)	19 (42)
Clinical score*		
Score 0	—	16 (36)
Score 1	—	12 (27)
Score 2	—	7 (16)
Score 3	25 (56)	6 (13)
Score 4	14 (31)	4 (9)
Score 5	6 (13)	—
Mean clinical score		
Mean ± SD (range)	3.6 ± 0.7 (3–5)	1.2 ± 1.2 (0–14)

* Number of clinical indicators of critical colonisation present
SD = standard deviation

Nine patients (20%) did not wear their compression therapy on each day of the four-week follow-up period; the remainder (80%) were concordant throughout.

Efficacy

All patients included were included in the efficacy analysis, and none were lost to follow-up despite the outpatient nature of this clinical trial.

At baseline, as stated above, all wounds had between three and five of the indicators for critical colonisation. By week 4, 36% (n=16) ulcers had no indicators remaining, while 22% (n=10) still had three to four. No study ulcers had all five indicators by the study end compared with 13% at baseline.

Table 2 shows the mean number of indicators from study start to completion. The reduction in number was highly significant ($p<0.001$).

Clinical-indicator percentages at baseline and study end are shown in Fig 1. The physicians documented the perilesional skin as 'healthy' in 17 patients (38% versus 13% at baseline). By the fourth week of treatment, mean ulcer surface area of granu-

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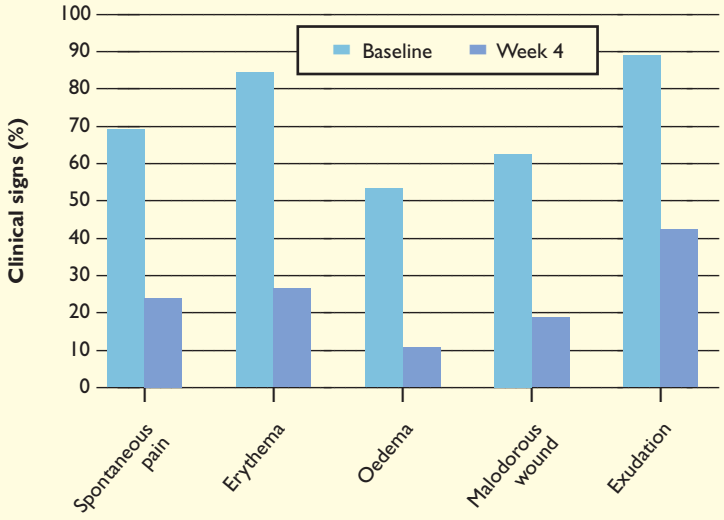
Fig 1. Percentage reduction in ulcer surface area over the four weeks of treatment



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lation tissue was 77% (versus 41% at baseline), slough was 23% (versus 58% at baseline) and necrosis 0.1% (versus 0.4% at baseline). Mean ulcer area reduction was 35 ± 58% (median 33%; $p<0.001$) after four weeks' treatment.

In the investigators' opinion:

- 11% of the ulcers healed (n=5) in a mean time of 22.4 ± 9.13 days
- 67% (n=30) improved
- 16% (n=7) were stagnating
- 7% (n=3) worsened.

Local tolerance (safety)

Three local adverse events, considered to be dressing related, were reported by the investigators:

- One patient developed 'moderate' contact dermatitis during the fourth week of treatment and was withdrawn from the study. This patient had a lesion at inclusion
- One patient experienced a burning sensation on the wound on the first day of treatment. The test dressing was discontinued and an alginate dressing applied. However, he was included in the analysis as it took account of the last evaluation available (LOCF)
- One patient experienced 'moderate' erythema beneath the test dressing after one week of treatment. However, use of the dressing continued and the erythema disappeared after a few days.

Dressing changes

In all, 470 care episodes were documented, representing 1250 cumulated days of treatment.

The studied dressing was removed every 2.66 ± 1.93 days (range 1–13). It was left in place for two days or more in 76% of cases. The nurses considered it easy to use and apply, and that it conformed well to the wound bed.

Discussion

The aim of this study was to evaluate the efficacy and safety of UrgoCell Silver in the management of venous or mixed leg ulcers with indicators of critical colonisation. The indicators studied are congruent with heavy bacterial colonisation.[2]

The total number of indicators significantly decreased during the four-week treatment period with the test dressing. This simple clinical score was shown to be sensitive to wound evolution, with an apparently limited inter-observer variability as reflected by the low variance of its distribution: the score decreased with the disappearance of the local clinical signs.

Indicators that appeared to be particularly responsive to the test dressing were malodour, wound pain and erythema, which is in line with other silver-dressing studies.[9,25]

Wound surface area reduction was noted in 35% of ulcers after four weeks of treatment. As this was not a controlled trial, it is difficult to compare these efficacy results with those of other silver dressings, as the leg ulcers in this trial will not always have the same characteristics as those in other clinical trials.[3,9,19,20,25]

Wounds at risk of infection are characterised by a high heterogeneity in their clinical characteristics and aetiologies. Therefore, even with a very large sample size, the influence of confounding factors cannot be ruled out, despite randomisation.[20]

Only three dressing-related local events were documented. All are often observed in leg ulcer management.[26,27]

The test dressing improved the perilesional skin: nearly 40% of the ulcers showed a healthy surrounding skin at the end of the treatment period compared with an 'altered' state in 87% of patients at baseline.

The acceptability of the dressing (ease of application and removal) to health-care professionals was good. Patients appreciated the painless dressing removal, which supports previous studies undertaken with neutral UrgoCell.[28]

The investigating physicians considered that the wounds improved (or healed) in nearly 78% of patients after four weeks of treatment, despite their poor prognosis[29] and considering the mean initial surface area (12.6cm^2) and ulcer duration (15.2 months).

These results suggest UrgoCell Silver had a favourable influence on the wound prognosis, and was well tolerated and well accepted in the treatment of venous leg ulcers with clinical signs of critical colonisation. However, a randomised clinical evaluation is required to confirm these encouraging clinical results. ■

Restore Foam Dressing Silver with TRIACT Technology,

Antimicrobial, Non-Adhesive with Non-Adherent Contact Layer,

DESCRIPTION

Restore Foam Dressing Silver Non-Adhesive is a non-adhesive, non-occlusive, antimicrobial absorbent dressing, composed of 3 layers:

- in contact with the wound, a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethylcellulose), cohesiopolymers, petrolatum and silver sulfate (3.22 mg/sq.in).
- a non-sensitising, super-absorbent polyurethane foam pad,
- a protective, semi-permeable polyurethane backing.

INDICATIONS FOR USE

The barrier functions of **Restore Foam Dressing Silver Non-Adhesive** may help reduce infection in moderately to high exuding partial and full thickness wounds, including partial thickness burns, pressure ulcers, venous stasis ulcers, diabetic ulcers and graft and donor sites.

MECHANISM OF ACTION

The proprietary TRIACT technology specificity lies in the presence of a polymer matrix which ensures cohesion of hydrocolloid particles and petrolatum on a polyester mesh.

In contact with wound exudates, the hydrocolloid particles combine with the matrix to form a lipido-colloidal gel, providing a moist environment that promotes healing. Being non-adhesive, removal of **Restore Foam Dressing Silver Non-Adhesive** is virtually pain-free and helps minimize damage to newly formed surrounding skin. It is ideal for use on wounds with fragile surrounding skin.

Restore Foam Dressing Silver Non-Adhesive was shown to be particularly effective against bacteria most frequently associated with wound infections. Under a log reduction in vitro test, he has demonstrated an antibacterial activity (at least 4 log reduction) against the following bacteria : Staphylococcus aureus, Streptococcus pyogenes, Pseudomonas aeruginosa (pyocyanic bacillus) and MRSA (strain ATCC 43300). The dressing sustains antibacterial activity for up to 7 days in in vitro studies.

The super-absorbent foam pad ensures drainage of exudates and helps protect the skin around the lesion from any maceration. The backing is soft, pliable and very comfortable; it allows the dressing to be easily shaped to the anatomical contours of the wound.

Restore Foam Dressing Silver Non-Adhesive is suitable for use under compression bandaging, due to the ability of the dressing to retain exudates.

DIRECTIONS FOR USE

- Clean the wound using sterile saline solution.
- Choose a dressing size which ensures that the dressing will cover the entire wound.
- Remove the protective tabs from the dressing.
- Apply the dressing directly to wound.
- Hold in place using a fixing bandage. Use a compression bandage when prescribed.
- Change **Restore Foam Dressing Silver Non-Adhesive** dressing every 1 to 3 days, depending on the wound and the healing progression.
- Duration of treatment is determined by the physician and depends on wound type and conditions.

WARNINGS AND PRECAUTIONS

- Concomitant use of other topical antimicrobial agent is not recommended.
- Use in pregnant or breast-feeding women and newborns has not been studied.
- Do not re-use the dressing.
- Store the dressing flat and at room temperature.

CONTRAINDICATIONS

- Known sensitization to silver and/or other dressings components.

HOW SUPPLIED

Restore Foam Dressing Silver Non-Adhesive is supplied in two sizes: 4" x 4" (10 cm x 10 cm) and 6" x 8" (15 cm x 20 cm).
A box contains 10 dressings.
Each dressing is individually packed in a sterile pouch.
Sterilization by radiation. Sterility is guaranteed unless a package is damaged or opened.
Single use only.

REF.: 509345: 4"x 4" (10 cm x 10 cm)
509346: 6"x 8" (15 cm x 20 cm)

Graphical Symbols
Symboles graphiques
Simbolos Gráficos

Attention: see instructions for use.
Attention: voir le mode d'emploi.
Atención: Vea las instrucciones de uso.

Single Use.
Usage unique.
No los use más de una vez.

Keep dry.
Conserver au sec.
Consérvelos secos.

USA: 1-800-323-4060
FAX Order: 847-680-1017
CANADA: 1-800-263-7400
FAX Order: 1-800-432-8846

ETATS-UNIS: 1-800-323-4060
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419124B

Restore

TRIACT TECHNOLOGY

INSTRUCTIONS/MODE D'EMPLOI/INSTRUCCIONES

Silver sulfate: 3.22 mg/sq.in
Sulphate d'Argent : 3,22 mg/po2
Sulfate de Plata : 3.22 mg/pulg.cuadrada

Foam Dressing Silver, Non-Adhesive
with Non-Adherent Contact Layer, Antimicrobial

Pansement hydrocellulaire Argent, Non-adhésif
avec interface non-adhérente, antibactérien

Apósito hidrocelular con Plata, No adhesivo
con capa de contacto no adherente, antimicrobiano

STERILE
STÉRILE
ESTÉRIL

Rx Only

Caution: Federal laws restricts this device to sale or on the order of a physician or licensed healthcare professional

Précaution : la loi fédérale exige de ce dispositif d'être vendu sur prescription d'un professionnel de la santé ou d'un médecin assermentés

Atención: Las Leyes Federales restringen la venta de este producto bajo prescripción bien sea de un médico ó licenciado en ciencias de la salud

hollisterwoundcare
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Restore pansement hydrocellulaire Argent avec la Technologie TRIACT,

Antibactérien, non-adhésif avec une interface non-adhérente

DESCRIPTION

Le pansement hydrocellulaire Argent Restore non-adhésif est un pansement non-adhésif, non-occlusif, antibactérien, absorbant, constitué de 3 couches :

- En contact avec la plaie, une trame polyester imprégnée de particules d'hydrocolloïdes (carboxymethylcellulose), de polymères, de vaseline et de sulphate d'argent (3.22 mg/po2).
- Une compresse de mousse polyuréthane super-absorbante, non-sensibilisante,
- Un support polyuréthane protecteur, semi-perméable.

INDICATIONS

De par son mode d'action antibactérien, **le pansement hydrocellulaire Argent Restore non-adhésif** est indiqué dans le traitement des plaies modérément à fortement exsudatives à risque d'infection, incluant les brûlures du 2nd degré, les ulcères veineux, les ulcères du pied diabétique, les escarres et les sites donneurs et en attente de greffes.

MODE D'ACTION

La spécificité de la technologie TRIACT réside dans la présence d'une matrice polymérique qui assure la cohésion des particules hydrocolloides et de la vaseline sur une trame polyester.

Au contact des exsudats, les particules hydrocolloides (CMC) se gélifient et forment un gel lipido-colloïde qui créé les conditions humides et favorise le processus cicatriciel.

Le pansement hydrocellulaire Argent Restore non-adhésif est indolore au retrait et n'endommage pas les tissus néoformés. Il est recommandé dans le traitement des plaies présentant une peau péri-lésionnelle fragile.

Le pansement hydrocellulaire Argent Restore non-adhésif est particulièrement efficace contre les bactéries les plus fréquemment responsables de la surinfection des plaies.

En effet, sur la base d'un test in vitro (réduction de log), il a démontré son activité (réduction d'au moins 4 log) sur les bactéries suivantes : Staphylococcus aureus, Streptococcus pyogenes, Pseudomonas aeruginosa (pyocyanic bacillus) and MRSA (strain ATCC 43300) et ceci pendant 7 jours.

La compresse de mousse super-absorbante assure un drainage des exsudats tout en aidant à protéger la peau d'éventuelles lésions et de macération.

Le support est doux, souple et très confortable ; il facilite la pose du pansement sur les contours anatomiques de la plaie.

Le pansement hydrocellulaire Argent Restore non-adhésif peut être utilisé sous compression, grâce à sa forte capacité de rétention des exsudats.

MODE D'EMPLOI

- Nettoyer la plaie avec du sérum physiologique.
- Choisir la taille du pansement appropriée afin de recouvrir toute la plaie.
- Retirer les ailettes de protection du pansement.
- Appliquer directement le pansement sur la plaie.
- Maintenir en place en appliquant une bande de fixation. Utiliser une bande de compression si elle est prescrite.
- Renouveler **le pansement hydrocellulaire Argent Restore non-adhésif** tous les 1 à 3 jours, en fonction de la plaie traitée et de son évolution.
- La durée du traitement est déterminée par le prescripteur et dépend du type de plaie et des conditions de cicatrisation.

MISES EN GARDE ET PRECAUTIONS D'EMPLOI

- L'utilisation conjointe avec d'autres traitements antiseptiques locaux n'est pas recommandée.
- L'utilisation pendant la grossesse, l'allaitement, chez le nouveau-né, n'a pas été étudiée.
- Ne pas réutiliser le pansement.
- Stocker le pansement à plat et à température ambiante.

CONTRE-INDICATIONS

- Sensibilisation connue à l'argent et/ou à d'autres composants du pansement.

PRESENTATION

Le pansement hydrocellulaire Argent Restore non-adhésif est disponible dans deux tailles :
4" x 4" (10 cm x 10 cm) et 6" x 8" (15 cm x 20 cm)
Une boîte contient 10 pansements.
Chaque pansement est conditionné individuellement sous sachet stérile.
Stérilisation par radiation. Le contenu est stérile sauf si l'emballage est ouvert ou endommagé.
Usage unique.

REF.: 509345 : 4"x 4" (10 cm x 10 cm)
509346 : 6"x 8" (15 cm x 20 cm)

Restore Apósito hidrocelular Plata con la tecnologia TRIACT,

Antimicrobiano, no adhesivo con capa de contacto no adherente

DESCRIPCIÓN

Restore Apósito hidrocelular con Plata No adhesivo es un apósito absorbente, no adhesivo, no-oclusivo y antimicrobiano, constituido por 3 capas :

- En contacto con la lesión, una red de poliéster impregnada de partículas de hidrocoloides (carboximetilcelulosa), de vaselina, de polímeros y de sulfate de plata (3.22 mg/pulg.cuadrada).
- Una compresa de espuma de poliuretano superabsorbente y no sensibilizante.
- Un soporte protector de poliuretano, semi- permeable.

INDICACIONES

Restore Apósito hidrocelular con Plata está indicado para reducir la infección para reducir la infección de heridas con exudación moderada ó alta, en heridas superficiales o profundas, incluso para quemaduras de segundo grado, úlceras por presión, úlceras varicosas, úlceras de pierna, úlceras diabéticas, injertos y donaciones.

MODO DE ACCIÓN

La tecnología TRIACT consiste en asociar una matriz polimérica que garantiza la cohesión de las partículas hidrocoloidales con una trama de poliéster impregnada de vaselina.
Las partículas hidrocoloides (CMC), al entrar en contacto con los exudados, forman un gel y forman, gracias a la matriz, una capa de contacto que crea las condiciones favorables para el proceso de cicatrización en medio húmedo.

Aunque **Restore Apósito hidrocelular con Plata No adhesivo** no es graso al tacto, su composición química queda grasa por lo que no se adhiere ni a la úlcera ni a sus contornos: los cambios de apósitos no son dolorosos ni traumáticos.

El Restore Apósito hidrocelular con Plata No adhesivo ha demostrado ser especialmente eficaz contra las bacterias que con más frecuencia se asocian a las heridas sobreinfectadas. De hecho, y basándonos en un estudio realizado in Vitro (reducción de log) se ha demostrado su actividad (reducción de al menos 4 log) sobre las bacterias siguientes: Staphylococcus aureus, Streptococcus pyogenes, Pseudomonas aeruginosa (pyocyanic bacillus) y MRSA (strain ATCC 43300) y esto durante 7 días.

La compresa de espuma de poliuretano, superabsorbante, asegura un drenaje de los exudados, favorece la protección de la piel perilesional de los fenómenos de maceración.
El soporte flexible, permite que el apósito se adapte bien a los relieves anatómicos de la lesión.

Se puede utilizar **Restore Apósito hidrocelular con Plata** bajo un vendaje compresivo elástico o no, puesto que el apósito retiene los exudados.

INSTRUCCIONES DE USO

- Limpiar la herida con suero fisiológico.
- Seleccionar un tamaño adaptado para que el apósito cubra toda la herida.
- Retirar las láminas protectoras del apósito.
- Aplicar directamente los apósitos sobre la herida.
- Sujete **Restore Apósito hidrocelular con Plata** con una venda de fijación o de compresión elástico si se prescribe.
- Los cambios se realizarán cada 3 o 4 días, en función de la herida a tratar y de su evolución.

PRECAUCIONES DE USO

- No se recomienda la utilización conjunta con otros antisépticos locales
- Su uso en mujeres embarazadas y recién nacidos no ha sido estudiado
- No uso el apósito de nuevo
- Conservar el apósito en posición horizontal, a temperatura ambiente

CONTRAINDICACIONES

- Hipersensibilidad conocida a la plata y/o a otros componentes de la malla.

PRESENTACIONES

Restore Apósito hidrocelular con Plata esta disponible en dos tamaños: 4" x 4" (10 cm x 10 cm) y 6" x 8" (15 cm x 20 cm)
Una caja contiene 10 apósitos.
Cada apósito está acondicionado individualmente en sobre estéril.
Esterilizado por radiación. La esterilidad queda garantizada salvo si el paquete esta dañado o abierto.
Uso único.

REF.: 509345: 4"x 4" (10 cm x 10 cm)
509346: 6"x 8" (15 cm x 20 cm)