Leg ulcers and the Urgocell Non-Adhesive wound dressing


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The enclosed peer-reviewed journal article is provided in the interest of free exchange of truthful scientific information. Restore® wound care dressings* are intended for single use in the management of partial- and full-thickness wounds.

In writing about the clinical trial, the authors note that the foam dressing was left in place in some cases for more than seven days at the granulation or epithelialization phases, or under a multilayer compression therapy. 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, Non-Adhesive 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® (Laboratoires URGO, Dijon, France) – is marketed in the U.S. by Hollister Wound Care LLC as Restore® Foam Dressing, Non-Adhesive with TRIACT™ Technology. (In the United States, lipidocolloid technology is known as TRIACT Technology.)

• 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
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S Fays, JL Schmutz, F Vin, V Thirion, M Sigal-Grinberg, S Ingen-Housz-Oro,
E Esteve, A Sauvadet, S Bohbot

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### Tissue Viability

**Leg ulcers and the Urgocell Non-Adhesive wound dressing**

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**Abstract**

The objectives of this clinical trial were to evaluate the efficacy and tolerance of the Urgocell Non-Adhesive (NA) dressing in the local management of venous or mixed leg ulcers. The study was a non-comparative, prospective, multicentre (15 centres) phase III, clinical trial. The studied population was composed of non-immunodepressed adults presenting a venous or mixed leg ulcer, uninfected, non-cancerous, present for less than 18 months. Patients were followed-up for 6 weeks with a weekly visit, including a clinical examination, area tracings and photographs. Evaluation by nursing staff and patients was performed at each dressing changed. Forty-three patients were included, presenting a leg ulcer with a mean surface area of 10.7 cm². The surface area was reduced by a mean of 38% after 6 weeks of treatment. Four local adverse events were deemed to be related to the tested treatment and acceptability was noted very good for patients and nursing staff. The Urgocell NA dressing, combined with compression therapy, promoted the healing of the chronic wounds under study. The good tolerance and acceptability of the tested dressings were greatly appreciated.

**Key words:** Dressings, Leg ulcers, Research and development

Leg ulcers have substantial medical consequences and considerable psychosocial repercussions. Venous leg ulcers and mixed leg ulcers predominantly of venous origin require a therapeutic approach that is based on two complementary methods: the application of the aetiological treatment, an effective venous compression, thereby treating the factor that triggers the ulceration, and local care by means of a suitable primary dressing placed in contact with the lesion and with surrounding skin (Philips et al, 2000).

Since the 1980s, the conventional greasy, non-absorbent wound dressings have been joined by modern dressings that constitute a veritable therapeutic alternative for the local management of chronic wounds. These include the hydrocolloids (adhesive dressings based on carboxymethylcellulose) which, in randomized clinical trials, have clearly demonstrated their advantages in the healing of chronic wounds (Friedman and Daniel, 1984; Gorse and Messner; 1987; Alm et al, 1989; Brandrup et al, 1990), under the concept of ‘healing in a moist environment’, as described in 1962 by Winter (1962, 1963).

Still more recently, and in a move to improve patient comfort (reduced dressing change frequency), dressings with a high-absorptive capacity, hydrocellular dressings, were developed and made available to the medical and paramedical staff (Pessenhofer, 1992; Zuccarelli, 1992; Bowszyc et al, 1995; Bale et al, 1997).

Laboratoires Urgo has developed a new wound dressing, Urgocell Non-Adhesive (NA), composed of a very absorbent expanded alveolar polyurethane foam and a useful surface area of 100%, meaning that it may be cut according to the wound surface. The wound and peri-lesional skin are covered by an Urgotul dressing which has been widely recognized as efficient in the healing process of chronic and acute wounds (Meaume et al, 2002; Letouze et al, 2004; Smith et al, 2004).

A clinical trial was then conducted to observe the performance (efficacy, tolerance and acceptability) of this new wound dressing in the treatment of venous or mixed leg ulcers.

**Materials and methods**

This was a phase III, multicentre clinical trial conducted in 15 investigating centres that included hospital dermatology and vascular medicine departments and private practice dermatologists and phlebologists. This non-comparative trial was prospective and included 43 patients (outpatients or patients initially hospitalized then discharged) presenting with venous or mixed leg ulcers (ankle brachial pressure index (ABPI) not less than 0.8) and treated for 6 weeks maximum. The study ulcer was to be between 3 cm² and 50 cm² in size and was not to have been present for more than 18 months. Clinically infected or cancerous ulcers were not to be included in this clinical trial.

The aetiology of the ulcers treated in this study was based on physical examination and on patient medical history which, in the vast majority of cases, was already well known and documented. It was not, therefore, considered necessary to perform a Doppler ultrasound systematically at the start of the trial.

**Ethics**

Ethical approval was obtained from the Lorraine Medical Ethics Committee in France. The study was conducted according to...
European regulations under ‘good clinical practice’. All subjects received detailed information on the study’s conduct and gave written consent.

**Trial treatment**

The Urgocell NA dressing (Cellosorb NA Laboratoires Urgo, Chenôve, France) is an absorbent, non-adhesive, non-occlusive dressing developed from lipid-colloid technology (TLC). It comprises three layers: a non-adherent, lipid-colloid interface (an Urgotul dressing in contact with the wound and peri-lesional skin), an intermediate layer composed of highly-absorbent polyurethane foam, and an outer layer made up of a non-woven, non-occlusive polyurethane support. Local cleansing operations were conducted exclusively with saline solution. The dressing was then applied directly to the wound bed and fixed by a support bandage. The study dressing may be cut, if necessary, as its whole surface is absorbent. The frequency with which the dressing has to be changed is dependent on wound condition and the volume of exudate. The investigators were asked to associate the tested dressing by static or removable compression, i.e. aetiological treatment essential for the management of such trophic disorders. However, while compression therapy was imposed by study protocol, its nature, i.e. using monolayer or multilayer, was left to the investigator’s convenience, owing to the fact the study involved different physicians.

**Endpoints**

The main endpoint was the reduction in wound surface area after 6 weeks of treatment by the Urgocell NA dressing. This was calculated from wound tracings made weekly (under a standardized procedure provided by the sponsor at the start of the trial). In addition to these tracings, the investigator also performed physical examinations and took photographs throughout the entire follow-up period. Secondary endpoints included tolerance, which was evaluated by the investigating physician during the weekly visits (occurrence of local adverse events).

The dressing acceptability was evaluated by the patient during each care operation, by the investigating nursing team and by visiting nurses when care was provided outside the hospital (ease of dressing use [application/removal], dressing conformability, painless/painful removal, odour).

**Statistical analysis**

The descriptive statistical analysis was performed on an intention-to-treat basis for both the principal and secondary endpoints and considered all the patients included in the trial.

**Results**

**Patients/study pathology**

Forty-three patients were recruited by 15 investigating centres for this clinical trial. Only one patient was lost to follow-up despite

<table>
<thead>
<tr>
<th>Table 1. Baseline demographic data</th>
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<tbody>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
</tr>
<tr>
<td>75±13 [37;96]</td>
</tr>
<tr>
<td><strong>Weight (kg)</strong></td>
</tr>
<tr>
<td>Female 67±15 [40;100]</td>
</tr>
<tr>
<td>Male 82±11 [62;106]</td>
</tr>
<tr>
<td><strong>Height (cm)</strong></td>
</tr>
<tr>
<td>Female 163±8 [150;194]</td>
</tr>
<tr>
<td>Male 176±6 [168;188]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Baseline ulcer’s characteristics</th>
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</thead>
<tbody>
<tr>
<td><strong>Duration of the ulcer (months)</strong></td>
</tr>
<tr>
<td>7.6 ±5.0 [1;18]</td>
</tr>
<tr>
<td><strong>Recurrent nature of the ulcer</strong></td>
</tr>
<tr>
<td>60.5%</td>
</tr>
<tr>
<td><strong>Initial surface area (cm²)</strong></td>
</tr>
<tr>
<td>10.71±7.31 [2.89;38.48]</td>
</tr>
<tr>
<td><strong>Location</strong></td>
</tr>
<tr>
<td>Right lower limb 19 (44)</td>
</tr>
<tr>
<td>Left lower limb 24 (56)</td>
</tr>
<tr>
<td>External malleolus 5 (12)</td>
</tr>
<tr>
<td>Internal malleolus 11 (26)</td>
</tr>
<tr>
<td>Supramalleolar 14 (33)</td>
</tr>
<tr>
<td>Submalleolar 2 (5)</td>
</tr>
<tr>
<td>Other 11 (26)</td>
</tr>
<tr>
<td><strong>Aetiology</strong></td>
</tr>
<tr>
<td>Venous 30 (70)</td>
</tr>
<tr>
<td>Venous, post-phlebitis 6 (14)</td>
</tr>
<tr>
<td>Mixed (arterial and venous) 7 (16)</td>
</tr>
<tr>
<td><strong>Condition of the peri-lesional skin</strong></td>
</tr>
<tr>
<td>Healthy 3 (7)</td>
</tr>
<tr>
<td>Inflammatory 24 (56)</td>
</tr>
<tr>
<td>Oedematous 15 (35)</td>
</tr>
<tr>
<td>Eczematous 3 (7)</td>
</tr>
<tr>
<td>Purpunc pigmented dermatitis 17 (40)</td>
</tr>
<tr>
<td>White atrophy 10 (23)</td>
</tr>
<tr>
<td>Irritated by the dressing(s) 5 (12)</td>
</tr>
<tr>
<td>Macerated 10 (23)</td>
</tr>
<tr>
<td>Other 9 (21)</td>
</tr>
<tr>
<td><strong>Spontaneous pain</strong></td>
</tr>
<tr>
<td>None 10 (23)</td>
</tr>
<tr>
<td>Mild 17 (40)</td>
</tr>
<tr>
<td>Moderate 10 (23)</td>
</tr>
<tr>
<td>Marked 6 (14)</td>
</tr>
</tbody>
</table>
| *Total different from 43 because several replies were possible
the outpatient nature of the trial. The trial population at inclusion was characterized by the parameters presented in Table 1.

With the majority of patients being women, nearly half the trial population had a history of cardiovascular disease (48.8%) and hypertension (37.2%), associated with a range of disorders related to the age of this population (e.g. diabetes, allergies, arthritis, dyslipidemia, Parkinson's disease, alcoholic neuropathy, prostate adenoma). Numerous parameters describing the studied ulcers were documented at inclusion and are presented in Table 2.

With a mean surface area of 10.71 cm², the ulcers had been present for an average of 7.6 months and were recurrent in more than 60% of cases. At inclusion, only 7% of the ulcers showed healthy peri-lesional skin: 63% of these lesions were surrounded by pigmented dermatitis and/or white atrophy, both being the expression of a long-standing venous disorder. In addition, at inclusion the ulcers were painful (moderate to marked pain) in 37% of the cases.

**Principal endpoint**
The investigating physician documented the planimetric evaluation (tracing) at inclusion and then on a weekly basis. This showed that mean surface area, which at inclusion was 10.71 ± 7.31 cm², fell to 7.67 ± 9.27 cm² after 6 weeks of treatment. Surface area reductions, given into percentage values, are shown in Table 3.

The surface area of treated ulcers was reduced by a mean of 37.9 % after 6 weeks of treatment, and two patients’ leg ulcers were healed before week 6. Figure 1 shows the percentage reduction in wound surface area over time.

After completing the 6 weeks of treatment, the investigating physicians considered that the wound was clinically improved in 73% of cases. Compression was combined with the trial dressing in 87% of the patients; among them, single layer was used for 86% of them and 14% of the patients had a multilayer compression therapy. The efficacy is illustrated by Figures 2–7.

**Secondary endpoints**

**Tolerance of the trial dressing:** The investigating physician documented the local tolerance of the treatment on a weekly basis throughout the 6 weeks of follow-up. A total of 11 local adverse events were reported: their occurrence led to only one definitive treatment discontinuation; no temporary withdrawal was reported. Four of these local adverse events, which were of the same nature and occurred in the same centre, were deemed to be treatment-related, although they did not require treatment discontinuation. The events mainly concerned erosion (in patients who presented with damaged peri-lesional skin at inclusion) and eczema lesions which disappeared when a corticosteroid-based ointment was applied to the peri-lesional area. The surrounding skin condition under study was also documented throughout patient follow-up.

After 6 weeks of treatment with the trial dressing, 34% of the ulcers were surrounded by healthy skin compared with 7% at inclusion.

**Acceptability of the trial dressing:** This clinical trial cumulated 1633 days of treatment and 521 local care operations were documented. Mean Urgocell NA application duration was 3.21 ± 1.83 days. This dressing change frequency was less than 3 days when the leg ulcer was highly exudative and sometimes exceeded 7 days at the granulation or epithelialization phases or under a multilayer compression therapy. Acceptability was evaluated by the nursing staff each time the dressing was changed, and this occurred throughout the entire duration of the trial. Acceptability results are presented in Table 4 and show that the trial dressing was well accepted by both patients and nursing staff.

**Discussion**
The objective of this clinical trial was to evaluate the efficacy and the acceptability of the Urgocell NA dressing in the treatment of venous leg ulcers or mixed leg ulcers predominantly of venous origin. Forty-three patients were included in 15 active centres. Each patient, treated for at most 6 weeks, was the subject of a weekly physical, planimetric and photographic evaluation by the investigating physician. In addition, the nursing staff present in the investigating department, or the visiting nurse in charge of the care at home, documented each care operation conducted between two consecutive weekly evaluations.

The non-controlled nature of this study makes the results more difficult to interpret. However, considering the type of wound treated in this trial (in a debridement phase, with healthy surrounding skin present in only 7% of cases), the investigators deemed the efficacy to be satisfactory.

The mean surface area reduction observed (37.9%) after 6 weeks of treatment in this clinical trial is comparable with literature data for studies conducted on ulcers of the same nature and type.
aetiology and with similar surface areas and durations at inclusion. For example, Vin et al (2002) reported that in a clinical trial comparing Promogran and Adaptic dressings applied for 6 weeks to treat ulcers of the same aetiology and of a similar size (7.0 cm² and 9.5 cm²), wound surface area was reduced by about 45% in the Promogran group and less than 30% in the Adaptic group (54.4% and 36.5% after 12 weeks of treatment with the Promogran and control group respectively).

Hansson (1998) reported ulcer surface area reductions of 62%, 41% and 24% after 12 weeks of treatment with a dressing based on cadexomer iodine, a hydrocolloid dressing and a paraffin gauze dressing, respectively (mean ulcer surface areas of 8.8 cm², 10.7 cm² and 7.1 cm² at inclusion).

Also, Thomas et al (1997) conducted a clinical trial to compare the Tielle and Granuflex dressings and observed a surface area reduction of about 45% and 35% respectively after 6 weeks of treatment. However, these ulcers were smaller at inclusion than those encountered in the Urgocell NA trial (4.31 cm² and 3.35 cm² respectively).

It was clearly reported in the literature by Margolis et al (2000) and Philips et al (2000) that leg ulcer healing rate correlates very strongly with two parameters — lesion size and duration — since ulcers heal more rapidly if they are initially less than 5 cm² in size and have been present for less than 6 months. The elevated absorption capacity of the Urgocell NA dressing meant that it only needed to be changed on average every 3.21 days.

Results reported in the literature (Dmochoska et al, 1999) show that absorbent dressings such as alginate and polyurethane...
foam dressings can be changed more frequently (every 2.46 and 2.39 days respectively on exudative ulcers). The same was also observed when considering hydrocolloid and hydrocellular dressings (2.7 and 2.8 days respectively) (Thomas et al, 1997). Additionally, Andersen et al (2002) reported dressing change frequencies of 2.1 and 3.3 days for two polyurethane foam dressings compared in a clinical trial.

It should be noted that 14% of the patients were treated with a multilayer compression therapy. The dressing in this patient subgroup was left in place for 7.9 ±2.0 days without any evidence of adverse event occurrence. This dressing change frequency is comparable with that described by Smith et al (2004a) (6.7±2.3 days) in a similar trial evaluating the Urgonol dressing combined with a K-Four multilayer compression.

### Table 4. Dressing acceptability

<table>
<thead>
<tr>
<th>Ease of application</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very easy/Easy</td>
<td>90.1</td>
</tr>
<tr>
<td>Difficult/Very difficult</td>
<td>9.9</td>
</tr>
<tr>
<td>Conformability to the wound bed</td>
<td></td>
</tr>
<tr>
<td>Very good/Good</td>
<td>85.9</td>
</tr>
<tr>
<td>Mediocre/Poor</td>
<td>14.1</td>
</tr>
<tr>
<td>Ease of removal</td>
<td></td>
</tr>
<tr>
<td>Very easy/Easy</td>
<td>98.6</td>
</tr>
<tr>
<td>Difficult/Very difficult</td>
<td>1.4</td>
</tr>
<tr>
<td>Pain on removal</td>
<td></td>
</tr>
<tr>
<td>None/Minor</td>
<td>96.4</td>
</tr>
<tr>
<td>Moderated/Marked</td>
<td>3.6</td>
</tr>
<tr>
<td>Odour</td>
<td></td>
</tr>
<tr>
<td>None/Moderate</td>
<td>96.8</td>
</tr>
<tr>
<td>Marked/Nauseating</td>
<td>3.2</td>
</tr>
</tbody>
</table>

In the clinical trial described here, the Urgocell NA dressing preserved (and in some cases improved) the condition of perilesional skin which was healthy in nearly 35% of the ulcers at the end of the treatment. All the patients included were analysed for tolerance (11 local adverse events); only four adverse events considered to be ‘certainly’ related to the treatment occurred and that was in one of the investigating centres.

The incidence of local adverse events with this new dressing was similar to (or lower than) that reported in the literature for comparable clinical trials (Hansson, 1998; Andersen et al, 2002; Vin et al, 2002). Finally, some rare and transient maceration effects were noted, probably as a result of the highly exudative nature of the treated ulcers. Such effects are also widespread with other types of dressings, and on occasion may require treatment discontinuation (Andersen et al, 2002).

Nursing staff evaluated the acceptability of the Urgocell NA dressing each time it was changed, and noted that it was very easy to use (dressing application and removal) and the patients particularly appreciated its pain-free removal.

The analysis of the clinical results in this French, multicentre clinical trial show that the Urgocell NA dressing is effective, safe and well accepted in the treatment of venous leg ulcers and mixed leg ulcers predominantly of venous origin, when used in association with a compression therapy.

### KEY POINTS

- A prospective, multicentre, non-comparative, phase III trial was undertaken to evaluate the efficacy and tolerance of Urgocell Non-Adhesive wound dressing, in the local management of venous leg ulcers.
- A 6-week follow-up on a weekly basis showed, on 43 patients, a mean ulcer area reduction of 38%.
- With a mean change frequency of 3.21 days, only four local adverse treatment-related events were noted.
- A very good acceptability for the patient (painless removal) and for the nursing staff (ease of use), was recorded.

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Restore Foam Dressing with TRIACT Technology, Non-Adhesive Dressing

DESCRIPTION

Restore Foam Dressing Non-Adhesive is a semi-permeable, non-adhesive absorbent dressing, composed of 3 layers:

• In contact with the wound, a polyester mesh impregnated with a matrix comprising of hydrocolloid particles (carboxymethylcellulose), cohesion polymers, petrolatum.
• A non-sensitizing, super-absorbent polyurethane foam pad.
• A protection, semi-permeable polyurethane backing.

INDICATIONS FOR USE

Restore Foam Dressing Non-Adhesive is indicated for the treatment of all types of moderate to heavily exuding chronic wounds (pressure ulcers, leg ulcers, diabetic foot ulcers) and acute wounds (partial thickness burns, dermabrasions, traumatic wounds, post-operative wounds, etc.).

MECHANISM OF ACTION

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

In contact with wound exudates, the hydrocolloid particles combine with the matrix to form a hydrophilic gel providing a moist environment that promotes healing. The removal of Restore Foam Dressing Non-Adhesive is virtually painless and helps minimize damage to newly formed surrounding skin. It is ideal for use on wounds with triple wwwing around skin.

The super-absorbent 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 adhere easily to the anatomical contours of the wound.

Restore Foam Dressing 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 size which ensures that the central pad will cover the entire wound.
• Remove the protective tabs from the dressing.
• Apply the dressing directly to wound.
• Hold in place using a filling bandage. Use a compression bandage when prescribed.
• Change Restore Foam Dressing Non-Adhesive every 3 to 4 days, depending on the wound and the healing progression.
• Duration of treatment is determined by the physician and depends on wound type and healing conditions.

WARNINGS AND PRECAUTIONS

• Do not reuse the dressing.
• Store the dressing flat and at room temperature.

CONTRAINDICATIONS

Restore Foam Dressing Non-Adhesive 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.

HOW SUPPLIED

Restore Foam Dressing Non-Adhesive is supplied in two sizes:

• 4" x 6" (10 cm x 15 cm), 6" x 6" (15 cm x 15 cm).
• Each 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: 509444: 4" x 4" (10 cm x 10 cm)
528446: 6" x 6" (15 cm x 20 cm)

Graphical Symbols

Symbols Graphiques

MITIGATION

Avoided non-instructions for use. No mitigation technique is approved.

SÉRÉE DU DÉPOT

No risk of deposit is expressed.

INSTRUCTIONS/MODE D'EMPLOI

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

Pansement hydrocollaïre, Non-adhésif avec interface non-adhérente

Apósito hidrocélular, No adhesivo con capa de contacto no adhesiva

STERILE

SÉRÉE

ESTÉRIL

SÉRÉE
Restore pansement hydrocellulaire avec la Technologie TRIACT,
Pansement Non-adhésif!

DESCRIPTION
Le pansement hydrocellulaire Restore Non-adhésif est un pansement semipermeable, absorbant, constituant de 3 couches :

- En contact avec la plaie, une trame polypropylène imprégnée de particules hydrocellulaires (cellulose microfilamente), de polymères et de vaseline.
- Une couche de mousse polypropylène superabsorbante, non-sensibilisante.
- Un support en polypropylène protecteur et semi-permeable.

INDICATIONS
Le pansement hydrocellulaire Restore Non-adhésif est indiqué dans le traitement de toutes les plaies modérément à fortement exsudatives, chroniques (ouvertures, ulcères de jambes et ulcères du pied diabétique) et agressées du 3ème degré, démarriages, plaies traumatiques, plaies post-opératoires, etc.

MODE D’ACTION
La spécificité de la technologie TRIACT reside dans la présence d’une matrice polyméthacrylique qui assure la coalescence des particules hydrocellulaires et de la vaseline sur une trame polypropylène.

Au contact des exsudats, les particules hydrocellulaires se pétètent et forment un gel polyalcoolique qui crée un environnement humide et favorise le processus cicatriciel.

Le recouvrement du pansement hydrocellulaire Restore Non-adhésif est holistique et n’entamante pas les flux de plaie. Ce pansement est recommandé dans le traitement des plaies présentant une peau péri-exsudative fragile.

La couche de mousse polypropylène super-absorbante assure un drainage des exsudats, tout en aidant à protéger le pansement contre le contact direct avec les exsudats.

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

Restore Apósito hidrocélulico con la tecnología TRIACT,
Apósito No adhesivo

DESCRIPTION
Restore Apósito Hidrocélulico No adhesivo es un apósito absorbente, no adhesivo, no rellenable, constituido por 3 capas :

- En contacto con la lesión, una red de poliéster impregnada de partículas hidrocelulólicas, en vaselina y de polímeros.
- Una capa de espuma de polímeros superabsorbente y no sensible.
- Un soporte protector de poliéster, semi-permeable.

INDICACIONES
Restore Apósito Hidrocélulico No adhesivo está indicado para el tratamiento de todo tipo de heridas crónicas con escaras de moderada a alta (áreas de presión, áreas de lesión de piel diabética) y heridas agudas quemaduras de segundo grado, dermo-abscesos, heridas traumáticas, heridas postoperatorias.

MODE DE ACCIÓN
La tecnología TRIACT consiste en una matriz polímerica que garantiza la coalescence de las partículas hidrocelulólicas con un círculo de poliéster impregnado de vaselina.

Las partículas hidrocelulólicas (CMC), al entrar en contacto con los exudados, forman un gel húmedo, gracias a la matriz, un cojinete de contacto que crea condiciones favorables para el desarrollo de una cicatrización en medio húmedo.

Aunque Restore Apósito Hidrocélulico No adhesivo no es graso al tacto, su composición química queda clara por lo que no se adhiera ni a la ropa ni a sus contornos los cambios de apósito no son dolorosos ni traumáticos.

La capa de espuma de polímeros superabsorbente asegura un drenaje de los exudados, favorece la protección de la piel perilesional de los fenómenos de maceración. El apósito flexible, permite que el apósito se adapte bien a las irregularidades de la lesión.

Es posible su uso Restore Apósito hidrocélulico No adhesivo bajo un vendaje compresivo elástico o no, que puede retener 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.
- Sujetar el apósito con una venda de fijación o de compresión elástica, si se precisa.

Los cambios de Restore Apósito Hidrocélulico No adhesivo se realizarán cada 3 a 4 días, en función de la herida a tratar y de su evolución.

PRECAUCIONES DE USO
- No usar apósitos de nuevo.
- Conservar el apósito en posición horizontal a temperatura ambiente.

CONTRARREACCIONES
- Restore Apósito Hidrocélulico No adhesivo no debe ser utilizado por individuos sensibles a que tal Reid iso sensación alérgica a la materia o a algún de sus componentes.

PRESENTACIONES
Restore Apósito Hidrocélulico No adhesivo está disponible en los formatos:
- 6 x 6 cm (10 cm x 10 cm) y 6 x 6 cm (15 cm x 20 cm)
- Una caja contiene 10 apósitos.
- Cada apósito está acondicionado individualmente en sobre aislado.
- Esterilizado por radiación, la esterilidad queda garantizada sólo si el apósito está dada o abierto.

Usos únicos.

REF.
- 520943: 4 x 4 cm (20 cm x 10 cm)
- 520934: 6 x 6 cm (30 cm x 20 cm)

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