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Biatain® Ibu
Product Monograph

Coloplast

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Biatain® Ibu

Table of contents

Preface

Many patients with chronic wounds experience pain that affects their quality of life and wound healing potential. According to literature up to 60% of leg ulcers are painful[1,2,3]. Wound pain should be addressed by holistic assessment and management. Local pain management is a natural first step in a holistic management approach.

This product monograph begins with a brief introduction to wound pain, followed by information for health care professionals on the conditions for clinical use of this wound dressing (medical device, class III). This device combines moist wound healing with local release of a low dose of ibuprofen. Clinical evidence supporting this device has been included, as well as a review of the active component of the device: ibuprofen.

The name of this device is ***Biatain Ibu***. It is a polyurethane foam dressing with ibuprofen incorporated into the foam. It is recommended for use in painful wounds of all types where exudate is present and infection has been excluded. In the presence of wound exudate ibuprofen is continuously released to the wound bed proving a pain reducing effect, whilst the foam dressing provides moist wound healing.

For additional healing and information on ***Biatain Ibu*** please check the website www.coloplast.co.uk

Peterborough, January 2014
Coloplast A/S

Management of painful chronic wounds

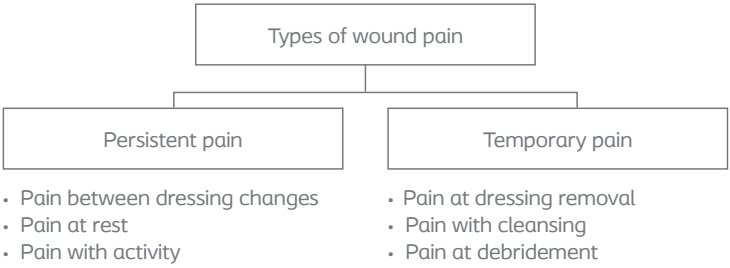
Introduction

The populations of North America and Europe are aging[4,5]. Chronic wounds are a serious problem among the elderly, involving different wound aetiologies including pressure ulcers, venous and arterial leg ulcers, and especially in people with diabetic foot ulcers. The presence of an ulcer has serious consequences for a patient's life. Affected individuals often report pain as dominant in their lives[6], and pain associated with chronic wounds should be handled with high priority. Symptomatic treatment of pain is part of a patient centred care pathway and must go hand-in-hand with treating the underlying aetiology or cause of the wound.

Patients with chronically painful wounds have reported decreased mobility, and a decline in family status[6-8]. In addition, Chase[9], Krasner[6] and Flanagan[10] reported that patients expected pain and considered the distress caused by unexpected fluctuating pain as a natural part of having an ulcer and being older.

Krasner[11] reviewed patients' experience of wound pain. Figure 1 gives a useful overview of her model. Patients described their agony as having a persistent pain feeling and/or a more limited temporary pain. In their interactions with patients, the pain model can be a useful guide for health care professionals to understand how patients with chronic wounds experience wound pain.

Figure 1 – A model of wound pain (modified from Krasner[11])



Persistent wound pain

Persistent pain, also known as chronic pain, in leg ulcers and other chronic wounds is often untreated[12]. This may partly be caused by lack of communication between patients and health care professionals[13,14] and partly caused by lack of appropriate scientific evidence. Briggs and Nelson[15] concluded their Cochrane review on chronic wound pain with the remark that no research has been carried out addressing the treatment of persistent ulcer pain separated from the pain associated with dressing changes.

Temporary wound pain

The primary function of temporary or acute pain is to warn of injury and prevent further tissue damage such as mechanical, thermal and chemical injuries[16]. When the painful stimuli decrease, pain is usually relieved[16].

Nociceptive and neuropathic wound pain

Health care professionals often use the definition of pain developed by the International Association for the Study of Pain (IASP)[17]. Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Thus there are always two components leading to pain, sensory (physical) and emotional (psychosocial), and both of these components should be assessed in all patients. Nociceptive pain has been defined as an appropriate physiological response to painful stimulus[17]. Neuropathic pain has been defined as an inappropriate response caused by a primary lesion or dysfunction in the nervous system[17]. For treatment of the sensory (physical) component, pain can be divided into nociceptive and/or neuropathic pain (Table 1). The emotional component of nociceptive and neuropathic pain is similar and therefore health care professionals often use similar treatments. Both types of pain are seen either alone or in combination in patients with persistent painful wounds.

Table 1 – Characteristics of nociceptive and neuropathic pain

	Type of pain	
Characteristics	Nociceptive pain	Neuropathic pain
Pain caused by	Tissue damage, acute and chronic inflammation[16,18]	Disrupted/damaged peripheral nervous system[16,18]
Pain is described as	Aching, throbbing, gnawing, tender[14]	Burning, stinging, shooting stabbing, cramp, numbness[14]

Pain management

Chronic painful wounds are most likely to occur in the elderly, and they often have multiple co-morbidities. Nemeth et al.[19] reported that 65% of all patients suffered from more than 4 co-morbidities including osteoarthritis, diabetes, angina, heart failure, peripheral vascular disease and myocardial infarction. Therefore, the elderly are often faced with potential poly-pharmacological problems. Any intervention that can decrease the likelihood of poly-pharmacology would be beneficial for the elderly segment of the population.

Many elderly see pain and disease as a natural part of getting older and are reluctant to ask for help, as they are worried about being perceived as 'complainers'[20]. The last thing they wish is to feel that they are wasting the time of health care professionals[14]. This is problematic, as untreated pain can affect the nerve system and can become chronic[20]. Chronic pain can lead to negative feedback, reducing the quality of life[7] and the general health status[7]. Therefore, the combination of treating wounds as well as the associated pain is likely to improve the patient's lives considerably.

Biatain – Ibu foam dressing

Biatain – Ibu foam dressing is unique as it combines the superior exudate management capacity of the Biatain foam dressing with a continuous release of a low dose of ibuprofen[10,21].

Biatain – Ibu consists of a soft, hydrophilic, non-adhesive polyurethane foam containing 0.5mg/cm^2 of ibuprofen homogenously dispersed throughout the matrix[10,21]. In the presence of exudate, there is a sustained release of a low dose of ibuprofen into the wound bed throughout the wear time of the dressing[21].

One dressing (10 x 12cm) contains 60mg of ibuprofen which is continuously released for up to 7 days[10,21], in proportion to the level of exudate. For comparison, the maximum daily oral dose of ibuprofen is 1200mg and in special cases 3200mg[23] for treatment of severe pain.

The structure of Biatain – Ibu ensures a high absorption and retention of exudate. The dressing is able to absorb large amounts of exudate locally with minimal dispersal, thus reducing the risk of leakage and maceration[24].

Biatain – Ibu is a sterile, single-use, soft, highly absorbent and conformable polyurethane foam dressing. Biatain – Ibu may be used throughout the healing process to provide protection for the indicated types of wounds. Biatain – Ibu is protected with a film backing that provides a bacterial barrier, is waterproof and semipermeable. Two versions are available: a non-adhesive version, which is suitable for use on fragile skin due to the absence of adhesive. The Soft-Hold version is an easy-to-apply, partially adherent layer, enabling the dressing to stay in place while a secondary dressing or compression therapy is applied or removed. The adherent layer covers less than 50% of the foam surface and has no effect on the dressing's moist wound healing properties, nor the ibuprofen release.

Indications*

Biatain – Ibu is indicated for painful exuding wounds, such as leg ulcers, pressure ulcers, diabetic foot ulcers, smaller second degree burns, donor sites, postoperative wounds and skin abrasions.

Biatain – Ibu provides moist wound healing and may reduce wound pain caused by tissue damage.

Biatain – Ibu is suitable for use where compression bandaging is indicated.

Contraindications

Do not use Biatain – Ibu on patients with a known sensitivity to ibuprofen or any of the dressing ingredients, aspirin or other related painkillers, especially when associated with a history of asthma, rhinitis or urticaria.

In case of suspected allergic reaction, contact Coloplast A/S for further information.

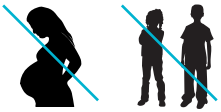
Do not use Biatain – Ibu during pregnancy.

Do not use Biatain – Ibu on children under 12 years of age except on the advice of a doctor.

Precautions

*Following information on Biatain – Ibu is according to obtained CD mark, Class III Medical Device.

Biatain® Ibu



Do not use Biatain – Ibu with hypochlorite or hydrogen peroxide. Biatain – Ibu must be removed prior to radiation treatment or examinations that include X-rays, ultrasonic treatment, diathermy, microwaves or MR scanning. The use of cleansing agents other than physiological saline or tap water, in combination with Biatain – Ibu has not been demonstrated. A health care professional should frequently inspect infected wounds, diabetic wounds and wounds which are solely or partially caused by arterial insufficiency.

Biatain – Ibu foam dressing clinical evidence

Introduction

An evidence-based and patient-centred approach are the cornerstones in the development of Coloplast A/S wound and skin care products.

According to the Centre of Evidence-Based Medicine, "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"[25].

Evidence-based medicine ensures that the treatment of patients with acute or chronic pathologies are supported by valid medical literature. Thus medical practitioners would select treatment options for specific cases based on the best research for each patient they treat.

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1. Combined use of an ibuprofen-releasing foam dressing and silver dressing on infected leg ulcers[26]

Jorgenson B. et al
Journal of Wound Care (2008) Vol 17, No 5, 210-4

Design

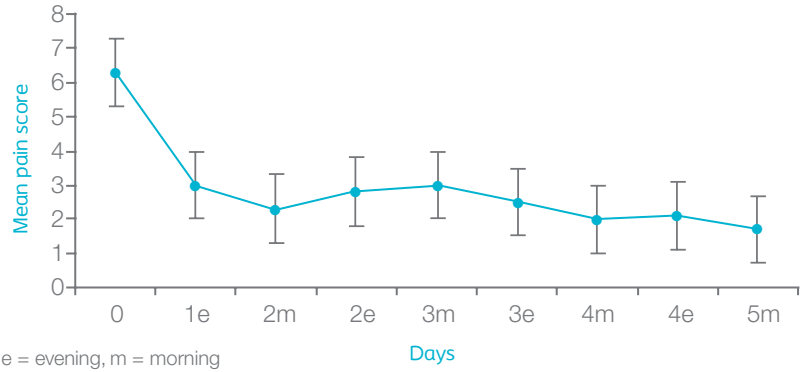
This open non-comparative study considered the safety and efficacy of silver releasing dressings used in combination with non-adhesive ibuprofen-releasing foam dressings in 24 elderly patients with painful, infected, exuding and delayed healing venous leg ulcers. The treatment period was 31 days with dressing changes on days 3 and 5 and as required thereafter. Compression therapy was mandatory two weeks before inclusion and throughout the study period. Patients were allowed to take oral pain-relieving medication throughout the study but the dose had to remain constant between days 1-5 when the intensity of chronic pain was assessed. Chronic pain was assessed twice daily on days 1-5 using an 11 point numerical box scale. Wound area and circumference, exudate handling properties, presence of malodour, ibuprofen concentration in the exudate and adverse effects were also assessed.

Results

Twenty three patients completed the study with one dropping out due to dressing related adverse event (non-allergic skin reaction). Nineteen patients took oral pain relieving medication (paracetamol, opioids, other) throughout the study.

Patients experienced a 50% reduction in chronic wound pain starting 12 hours after the first dressing application and remaining low for the first 5 days (figure 1).

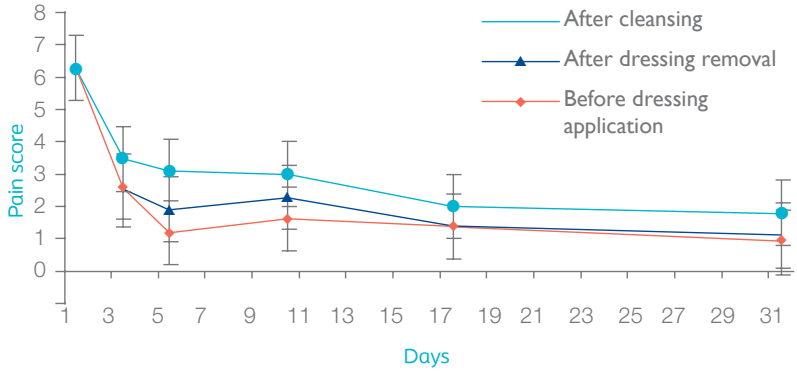
Figure 1 – Mean pain score for persistent pain.



e = evening, m = morning

Pain associated with dressing change also reduced rapidly remaining low throughout the 31 days study period (figure 2).

Figure 2 – Mean pain score for temporary pain at dressing change.



Improvement in wound pain was accompanied by a mean relative wound area reduction of 42% (a 20-40% reduction in wound area within 2-4 weeks is a reliable predictive indicator that healing will occur at 12 weeks). Wound malodour was reported in 9 patients (37%) at inclusion which had reduced to 2 patients (8%) at day 9 and 1 patient (4%) by the end of the study. Exudate handling was rated as excellent in 86% of the dressing changes and there was little or no leakage outside the dressing area in 92% of cases.

Four dressing related adverse events were observed (dermatitis & local irritation/maceration).

Conclusion

This dressing combination provided rapid relief of temporary and chronic wound pain while promoting healing of locally infected, exuding venous ulcers.

2. Pain and quality of life for patients with venous leg ulcers: proof of concept of the efficacy of Biatain-Ibu, a pain reducing wound dressing[21]

Jorgensen B.
Wound Rep Reg (2006) Vol 14, 233-9

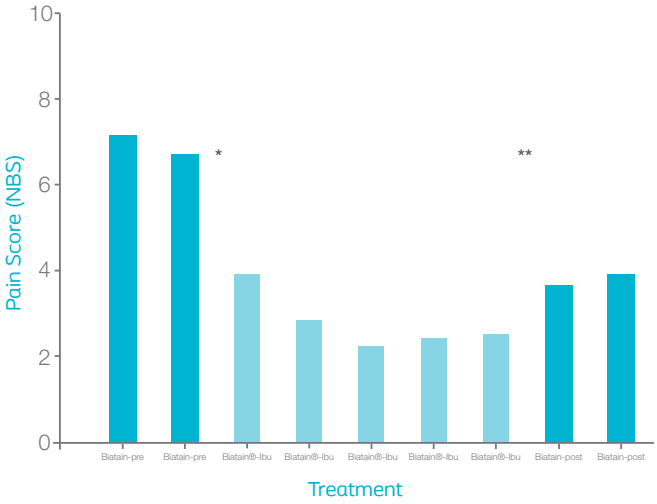
Design

Ten elderly patients with painful venous leg ulceration were included in this 3 week single blind crossover study. The study involved a pre-treatment period with two placebo foam dressings (Biatain pre), a test treatment period of five active foam dressings containing ibuprofen (Biatain-Ibu) and a washout period with two placebo foam dressings (Biatain-post). A further two patients with painful venous ulcers experienced similar treatment over 8 days with additional blood sampling. Pain during dressing change was also assessed. Compression therapy was mandatory throughout the study period. Patient's pain was evaluated with a numerical box scale with quality of life assessed using the WHO-5 Well-Being Index. Dressing safety measures included wound exudate leakage, impact on the local wound environment and ibuprofen concentration in blood plasma and wound exudate.

Results

Treatment with Biatain–Ibu delivered a significant decrease in pain intensity scores from 7 in the pre-treatment phase to approximately 2.5 in the Biatain-Ibu treatment phase. Post-treatment pain levels were significantly higher than observed during the active treatment (figure 1).

Figure 1 - Pain intensity measurements determined just before dressing change sessions.



The pain was measured just before dressing change using the NBS scale. Biatain®-Ibu group was significantly different from the Biatain-pre group; and Biatain®-Ibu was different from the Biatain-post group.

Pain levels during dressing changes correlated with levels before dressing changes thus wearing Biatain-Ibu before dressing changes reduced pain during dressing changes. All five questions in the WHO-5 Well-Being Index (good, mood, calm, relaxed, active and vigorous) were statistically improved during the Biatain-Ibu treatment period.

Biatain-Ibu did not cause detectable levels of ibuprofen in any of the blood samples.

There was no significant difference in wound exudate leakage, odour, itching inflammation and peri-ulcer skin problems between Biatain-Ibu and Biatain (pre and post). However stinging was significantly less severe and there was a tendency towards less bleeding with Biatain-Ibu at dressing changes.

Conclusion

When compared with Biatain, Biatain-Ibu provides a rapid decrease in pain intensity along with a significant increase in quality of life in elderly patients. Reduction in chronic wound pain and improved quality of life can promote faster wound healing. Ibuprofen was not found in blood plasma during treatment with Biatain-Ibu which avoids the adverse effects of systemic analgesia and the potential for interaction with other drugs elderly patients will be taking.

3. Effect of an ibuprofen-releasing foam dressing on wound pain: a real life RCT[27]

Domenech R.P. et al
Journal of Wound Care (2008) Vol 17, No 8

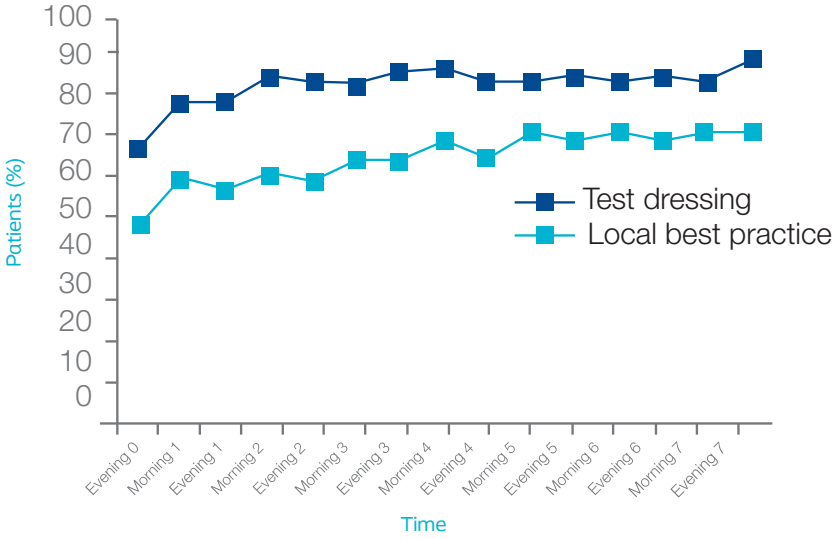
Design

A multicentre comparative controlled parallel group study where 853 elderly patients were randomised to either an ibuprofen-releasing foam dressing or local best practice. Local best practice is the current standard treatment used in each clinic for exuding painful wounds and included foams, hydrogel, hydrofiber, hydrocolloid and gauze dressings. Patients had painful wounds of different aetiologies including leg ulcers, vasculitic ulcers, pressure ulcers, diabetic foot ulcers, burns, traumatic injuries, skin abrasions and postoperative wounds. Treatment period for the study was 7 +/- 2 days. The primary end-point was relief in persistent wound pain from day 1-7 using a five point verbal rating scale.

Results

Patients total pain relief scores were significantly in favour of the ibuprofen-releasing foam dressing. Almost 80% of patients using the ibuprofen-releasing foam dressing experienced pain relief within the first 24 hours compared with 59% in the local best practice group (figure 1.)

Figure 1 - Percentage of patients who reported slight or more pain relief during the study period



The overall pain relief experienced during wear time and at dressing change was significantly better in the ibuprofen-releasing foam dressing than in the local practice group (figures 2 & 3).

Figure 2 - Pain relief during wear time

Figure 3 - Pain relief at dressing change

Quality of life measures using the WHO-5 index were significantly higher in the ibuprofen- releasing foam dressing treatment group as were the four parameters of activities of daily living measured (appetite, overall well-being, mobility and social activity).

Adverse events were very low in both groups.

Pain relieving medication was taken by 74% of patients for wound pain prior to and during the study. Despite not being asked to alter the dosage, 39% of patients in the ibuprofen-releasing foam group reduced dosage compared with 19% in the local best practice group.

Conclusion

The ibuprofen-releasing foam dressing is effective in relieving chronic wound pain with most patients experiencing a fast onset of action usually within the first 24 hours. Pain at dressing change is also significantly better with the ibuprofen-releasing foam dressing. This along with reduction in leakage, improvements in quality of life and activities of daily living and minimal adverse effects demonstrates that this ibuprofen-releasing foam dressing is an effective solution for the management of exuding painful wounds of different aetiologies.

4. Analgesic efficacy of an ibuprofen-releasing foam dressing compared with local best practice for painful exuding wounds[28]

Arapoglou V. et al
Journal of Wound Care (2011) Vol 20, No 7, 319-325

Design

This report is a secondary analysis to re-examine data from the Domenech et al study[27] with respect to pain relief outcome and wound aetiology, variables not considered in the original evaluation. The raw data was also re-analysed using improved more robust measures for analgesic efficacy. Five patient groups with different wound aetiologies were identified – venous arterial and mixed leg ulcer comprised 48%, 11% and 17% respectively of the 688 elderly patients included in this analysis with vasculitic (5%) and traumatic (18%) aetiologies comprising the remainder. The main end-point of the analysis was the proportion of patients who, from day 1 to day 5, reported a summed pain relief score >50% of the total maximum pain relief score. From this a number needed to treat (NNT) for ibuprofen releasing foam versus local best practice was derived.

Results

For the overall study population the percentage who on day 5, reported a summed pain relief score of >50% was significantly higher in the ibuprofen releasing foam dressing group (55%) than the local best practice group (24%) giving an overall NNT of 3.2. Differences across the groups ranged from 19% for venous leg ulcers to 41% for arterial leg ulcers with NNTs ranging from 5.2 to 2.4 respectively (table 1). After the first day of treatment 20-32% of patients in the ibuprofen releasing foam dressing group reported >50% pain relief compared with 4-10% of patients in the local best treatment group.

Table 1 – Proportion of patients who reported a summed pain relief score >50% of the total maximum pain relief score for day 1 to 5 ($TOTPAR_{D5>50\%}$).

Wound aetiology	Ibuprofen foam (%)	LBP (%)	p value	NNT
Venous leg ulcer	49	30	0.0003	5.2
Arterial leg ulcer	68	27	0.0003	2.4
Mixed aetiology	55	25	0.0003	3.3
Vasculitis	43	13	0.0013	3.3
Traumatic	62	23	<0.0001	2.6
Total	**55**	**24**	**<0.0001**	**3.2**

NNT = number needed to treat

Conclusion

Ibuprofen releasing foam dressings provided clinically meaningful and swift pain relief in significantly more patients than current local best treatment, across a range of different types of chronic and traumatic, painful, exuding wounds. The overall NNT for ibuprofen-releasing foam dressings of 3.2 compares favourably with NNTs for oral analgesics in chronic pain of 3-5 which are considered to offer effective pain relief.

5. Clinically relevant pain relief with an ibuprofen-releasing foam dressing: Results from a randomised, controlled double blind clinical trial in exuding, painful venous ulcers.[29]

Fogh K. et al
Wound Rep Reg (2012) Vol 20 815-821

Design

A 6 week multicentre double blind randomised controlled trial comparing the performance of ibuprofen foam dressing (Biatain-Ibu) with comparator foam dressing without added ibuprofen (Biatain Non-Adhesive). Study population consisted of 120 elderly patients (60 in each group) with chronic, exuding, painful venous ulcers of the lower limb. The primary outcome measure was clinically relevant pain relief (PAR) compared to baseline pain, during the first 5 days of the study. The main end-point was the proportion of "responders " in each treatment group with responders defined as patients who, when their reported PAR scores were added from day 1 to day 5, had a summed PAR score of at least 50% of the maximum total PAR score. Wound related parameters such as ulcer healing, ulcer area reduction and peri-ulcer skin condition were also studied.

Results

Clinically relevant pain relief (PAR) was significantly greater in the ibuprofen-releasing foam dressing group than in the comparator foam dressing group (figure 1). There were 34% responders at the 50% cut off point (patients with at least 50% PAR) in the treatment group compared with 19% in the comparator group giving a number needed to treat (NNT) of 6.8. The percentage of patients with clinically relevant pain relief increased over time in both groups and especially in the group treated with the ibuprofen foam dressing.

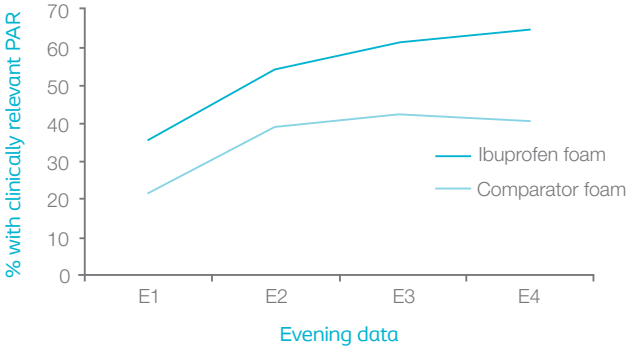


Figure 1 - The figure shows the percentage of participants with clinically relevant PAR (2: "moderate," 3: "marked," or 4: "complete") at each evening measure (day 1 to 4).

Fourteen adverse events were reported in the ibuprofen foam dressing group of which 4 were reported as related or possibly related to the use of the dressing (eczema and wound infection). Nine adverse events were reported in the comparator group of which 6 were reported as being related or possibly related to dressing (eczema and increased wound pain).

Conclusion

The ibuprofen-releasing foam dressing (Biatain-Ibu) produces clinically relevant pain relief for patients with painful exuding venous leg ulcers with a number needed to treat (NNT) of 6.8. This NNT is comparable to NNTs from oral and topically applied NSAIDs for chronic pain. Wound healing and numbers of adverse events were comparable in the two patient groups.

6. Reducing wound pain in venous leg ulcers with Biatain IBU : A randomised controlled double-blind clinical investigation on the performance and safety[30]

Gottrup at al
Wound Rep Reg (2008) Vol 16, 615-625

Design

A multicentre randomised controlled double blind parallel group study comparing the performance and safety of ibuprofen foam dressing (Biatain –Ibu) with a comparator (Biatain Non-Adhesive) in 122 elderly patients with chronic venous leg ulcers of the lower limb of more than 8 weeks duration. The study was double blind from days 1-42 and single blind from days 43-47. For this last period all patients were treated with the comparator dressing. Patients were required to receive compression therapy for at least 2 weeks before inclusion and throughout the study. The primary outcome measure was pain relieving effect at days 1-5. Persistent and temporary pain (dressing change related) was assessed at days 1-5 and at days 43-47. Pain relief was assessed using a five point verbal rating scale with pain intensity measured on a validated 11 point numeric box scale.

Results

Compared with the comparator significantly more patients treated with the ibuprofen foam dressing experienced wound pain relief starting on the first evening and continuing throughout the 5 days of wear time. On the first evening 74% of the ibuprofen foam group had pain relief compared with 58% in the comparator group (figure 1.) Wound pain intensity levels were reduced by 40% with the ibuprofen foam compared with 30% with the comparator.

Although it was not possible to detect a difference in dressing change pain at days 1-5, pain intensity increased in the former ibuprofen-treated group when the non-adhesive comparator was introduced between days 43-47.

Ulcer healing rates, ulcer area reductions and adverse events were similar in both treatment groups and both treatments improved indicators used to assess patient's quality of life.

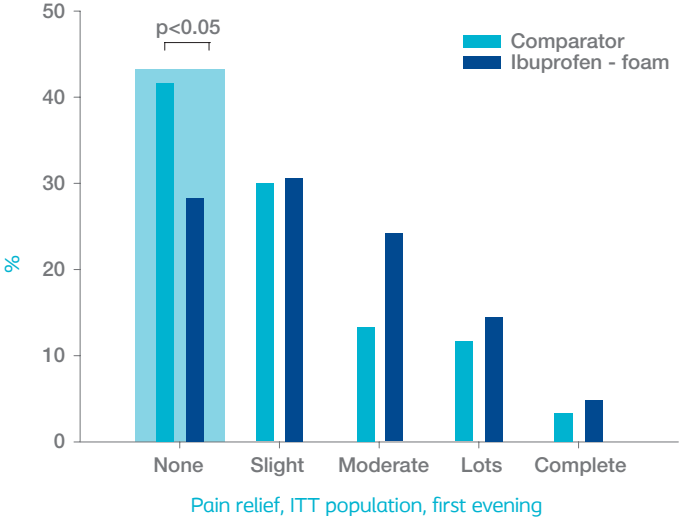


Figure 1 – Pain relief measured the first evening according to the five-point verbal rating scale (VRS). The light blue box indicates the first evening where 28% more persons had pain relief in the Ibuprofen-foam group, than the comparator group ($p < 0.05$). In the Ibuprofen-foam group 74% of the patients experienced pain relief and 58% in the comparator group.

Conclusion

More patients experienced pain relief with the ibuprofen foam dressing, and rated their pain relief higher than with the non-adhesive comparator. Intensity of pain was also reduced and the ibuprofen foam dressing provided rapid pain relief. Improved pain management was achieved without compromising wound healing or patient safety.

7. Evidence on wound types

Biatain – Ibu has been tested on a wide range of wound types. Table 1 indicates wound type, the primary finding, and the references to the published results.

Table 1 - Wound types and evidence

Type of wound	Primary findings	No. of patients	Ref.
Venous	Biatain – Ibu reduces pain (and provides pain relief) and was safe to use	616	10,21,27,28, 31,32,33
Arterial	No sub analysis performed, but overall better pain relief and reduced pain intensity observed	97	27,32,33
Mixed leg ulcer	Biatain - Ibu effective in relieving chronic wound pain with fast onset of action	116	27
Pressure	No sub analysis performed, but overall better pain relief and reduced pain intensity observed	15	32,33
Donor site (skin graft harvest site)	Biatain – Ibu provided rapid pain relief within the first day after application of Biatain – Ibu and throughout the 10-day study period. Healing was no different than local best practice.	10	34
Vasculitis	Biatain – Ibu improved pain associated with vasculitic leg ulcers (an average of 3 points on 11 point scale)	3	35
Oncology	Biatain – Ibu reduced pain from 7-9 to 2-3 on two oncology wounds treated with chemotherapy or radiotheraphy.	2	36

8. Summary of evidence on Biatain - Ibu

The non-clinical and clinical investigational programme on Biatain – Ibu has demonstrated that the dressing is effective in providing moist wound healing and at the same time reduces pain caused by tissue damage[10,21,26,27,28,29,30]. The clinical studies have demonstrated that the dressing improves the quality of life for patients experiencing persistent wound pain[10,21].

Furthermore, Biatain – Ibu combines superior exudate management and continuous release of ibuprofen[21,22], and releases ibuprofen locally with no observed systemic effect[21].

Biatain® Ibu

Ibuprofen Review – Refresher for Tissue Viability Nurses

Introduction

Prostaglandins are generated as a result of tissue damage and are a major component of the inflammatory process. They have been identified in all inflamed and damaged tissues. Prostaglandins increase inflammation and activate nociceptors whose function is to transmit pain impulses to the brain, thereby inducing pain. (Figure 1).

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic properties. It operates by blocking the cyclooxygenase enzymes (COX) thereby inhibiting prostaglandin synthesis and providing anti-inflammatory and analgesic benefits. (Figure 1)

Ibuprofen can be given systemically (oral, intravenous or rectal) or locally (topical) either in the form of a gel or included in foam dressings (Biatain-Ibu). Ibuprofen is the most commonly used and frequently prescribed NSAID due to is efficacy and low incidence of adverse effects. The most serious adverse effects from systemic ibuprofen are gastrointestinal and renal damage. However following use of Biatain-Ibu it has not been possible to detect ibuprofen in blood therefore these adverse effects are extremely unlikely with Biatain-Ibu.

Figure 1

Painful and inflammatory chemicals such as prostaglandins are generated in damaged tissue[34].

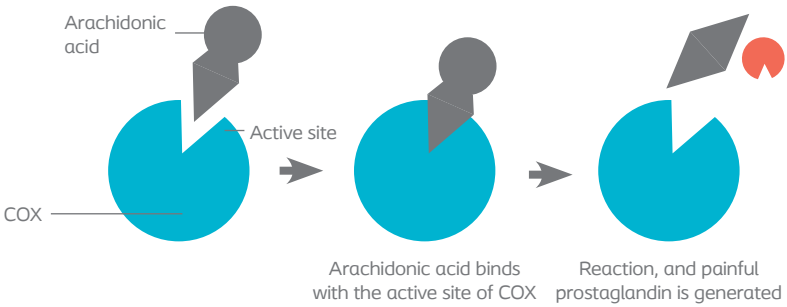
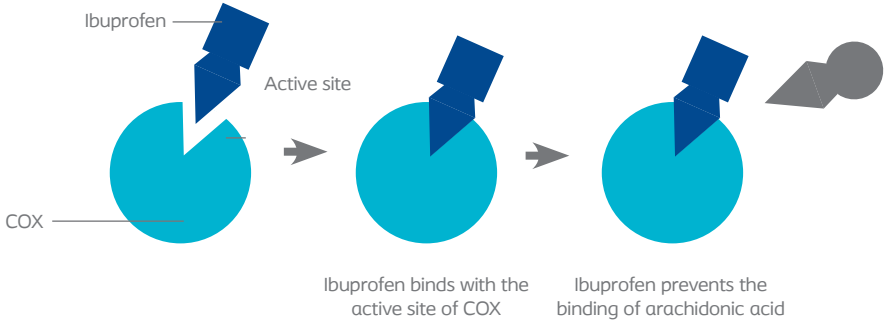


Figure 2

Ibuprofen blocks the excretion of painful and inflammatory chemicals such as prostaglandins[34].



Ibuprofen and wound healing

Ibuprofen has an anti-inflammatory effect, therefore speculation has been ongoing in literature whether ibuprofen will impair wound healing, as the process in which compounds important for the inflammation stage are produced, will be inhibited[35-38].

Wound healing in acute wounds is very different from chronic wounds, as indicated in the table below.

Table 1 - Differences between chronic and acute wounds

Acute wounds	Chronic wounds
Normal blood circulation system	Blood circulation is weak and often insufficient blood reaches the wound
Inflammation is a normal process in wound healing	Chronic inflammatory status, with active leukocytes, keep the wound in a painful non-healing state[39]

Data from several clinical studies with painful leg ulceration demonstrated similar wound healing properties with Biatain – Ibu and Biatain.[10,21,26,29,30]

In one study, the average reduction in ulcer size was measured to be 23% after 3 weeks' treatment[21]. This is comparable to results after 3 weeks from an earlier reported study on two commercially available foam products[24].

Reducing pain may have a general positive effect on wound healing[40]. In the case of venous leg ulcers, compression bandaging is required for healing. More than 50% of venous leg ulcer patients cannot tolerate compression because of the associated pain[40]. Biatain – Ibu can provide a special benefit for this group of patients.

Special considerations

Can Biatain – Ibu increase the risk of infection?

No, in the clinical studies involving more than 350 patients there has been no differences in number and type of infections between Biatain – Ibu against other moist wound healing dressings.

Ibuprofen inhibits inflammation, but will Biatain – Ibu inhibit the healing process?

No. This relationship has not been observed with current studies on low dose sustained released ibuprofen from Biatain – Ibu.

In more detail

It is known that acute inflammation shortly after wounding plays a role in the healing process but that chronic prolonged inflammation is often harmful.

1. Ibuprofen has an anti-inflammatory effect and some literature discusses the effect of ibuprofen on wound healing. Theoretically, higher doses of ibuprofen could inhibit the normal inflammatory wound healing stage,

2. The studies on Biatain – Ibu have so far shown no delay in wound healing when compared to Biatain or local best practice.[10,21,27,28,35]

Does Biatain – Ibu reduce pain at dressing change?

Yes, four independent clinical studies with more than 400 patients have demonstrated reduced pain at dressing change in addition to a reduction in the persistent pain between dressing changes.

Can wounds with heavy exudate overload the wound with a high level of local ibuprofen that may lead to unwanted adverse effects?

By following the Instruction For Use, an overload is not possible
[1200cm^2 = 10 dressings x (10 x 12)cm].

What are the side effects of using Biatain – Ibu?

There has been no difference in observed side effects between Biatain – Ibu and Biatain. Ibuprofen did not alter the safety profile of the moist wound healing dressing.

Can Biatain – Ibu be used on Diabetic Foot Ulcers?

Yes, but moist healing may be contraindicated if the wound does not have enough blood supply to heal and neuropathic pain common with persons with diabetes may not respond to the NSAID classes of pain agents.

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Biatain Ibu

Ordering Information

Biatain® Ibu *Non-Adhesive*

3DFit® Technology

Size (cm)	Quantity	Code	NHS	PIP
5x7	5	4105	ELA408	346-6430
10x12	5	4152	ELA320	327-0436
10x22.5	5	4158	ELA304	327-0451
15x15	5	4155	ELA322	327-0444
20x20	5	4120	ELA403	346-6422

Biatain® Ibu *Soft-Hold*

3DFit® Technology

Size (cm)	Quantity	Code	NHS	PIP
10x12	5	4162	ELA332	327-0469
10x22.5	5	4168	ELA302	327-0485
15x15	5	4165	ELA331	327-0477

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