



THE HEALING PROCESS



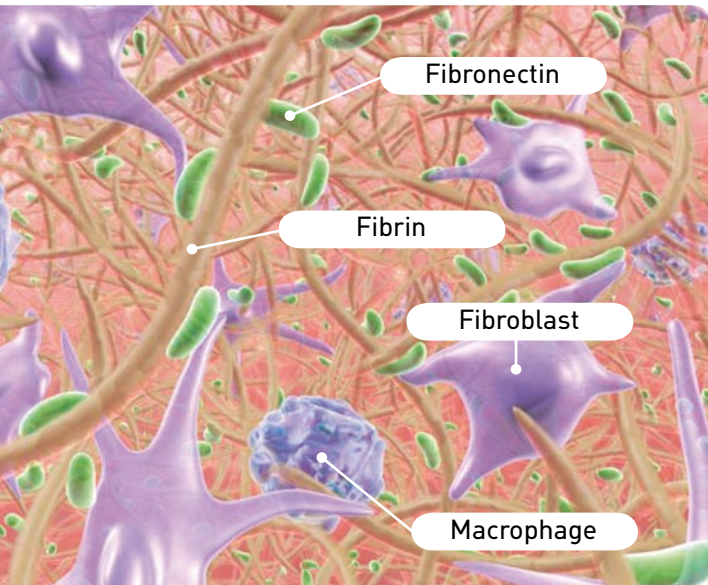
 **Xelma**[®]
EXTRACELLULAR MATRIX PROTEIN



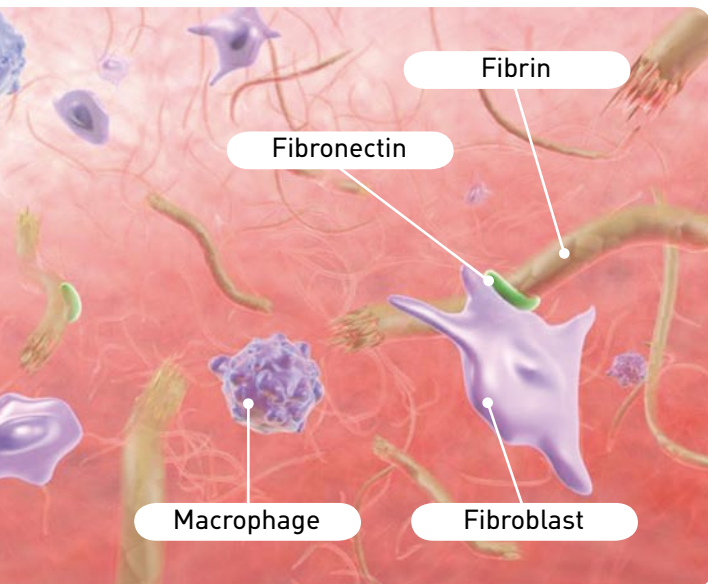
Restore the normal repair process in diabetic foot ulcers and other wounds associated with delayed healing

 **MÖLNLYCKE**
HEALTH CARE

Cells adhere to ECM during wound healing



Malfunctioning ECM in hard-to-heal wounds



A functioning extracellular matrix (ECM) is crucial for tissue regeneration and repair

The ECM plays an important role in the wound healing process. It acts as a scaffold within the wound, providing a framework to which cells can attach, proliferate and synthesise growth factors and ECM components.¹

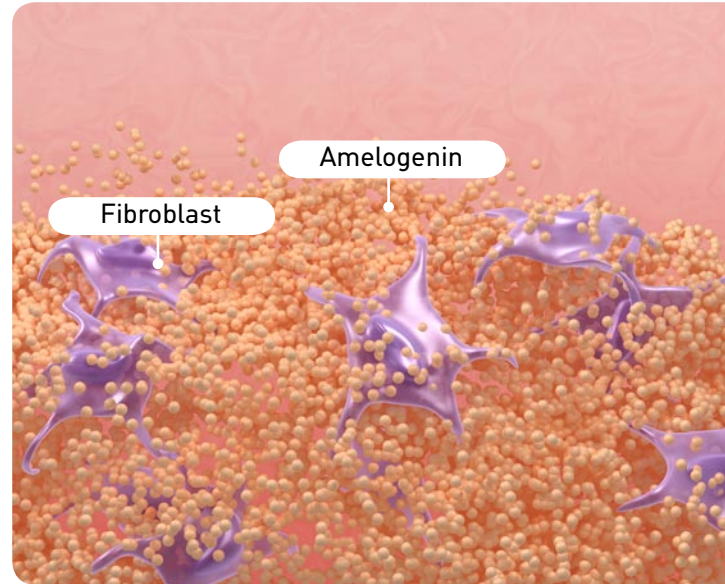
When the extracellular matrix malfunctions, as happens in the case of chronic wounds, there's nothing for the cells to attach to. In hard-to-heal wounds, a malfunctioning ECM compromises tissue remodelling and re-epithelialisation. In other words, it delays healing.

Chronic wounds are often associated with pain which can negatively impact upon patient quality of life. The cost of treating non-healing wounds can be up to three times greater than for healing wounds.²

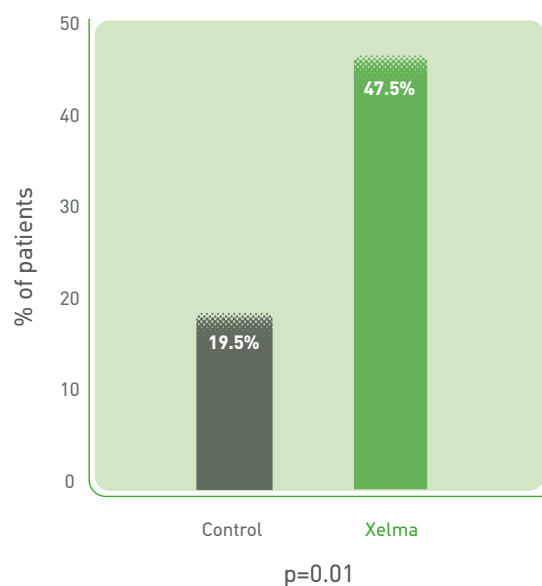
Xelma[®] gets healing started

Xelma is an extracellular matrix protein indicated for hard-to-heal wounds without clinical signs of infection such as venous leg ulcers, diabetic foot ulcers and pressure ulcers. Xelma's protein, amelogenin, provides a temporary ECM for cells to attach to, thereby restoring the natural healing process.

Amelogenin provides a temporary ECM for cell attachment



Percentage of patients demonstrating ulcer improvement (>50% reduction in size) -
Xelma plus high compression versus high
compression therapy alone (control)



Xelma is beneficial in the
treatment of hard-to-heal venous
leg ulcers that have failed to heal
with standard therapy³

How Xelma works

1. When Xelma is applied to a wound, amelogenin proteins assemble into aggregates that facilitate cell attachment
2. Once attached, fibroblasts are able to migrate, proliferate and synthesise growth factors and new ECM components
3. When functioning properly, the cumulative effect of new cells and ECM growth triggers normal wound healing

What is amelogenin?

Amelogenin is a biocompatible ECM protein that does not naturally participate in the wound healing process. However, it has similarities with other ECM proteins that participate in normal wound healing such as fibronectin. As ECM proteins, amelogenin and fibronectin have many similarities, especially the key property of cell adherence.



Proven effectiveness on hard-to-heal wounds

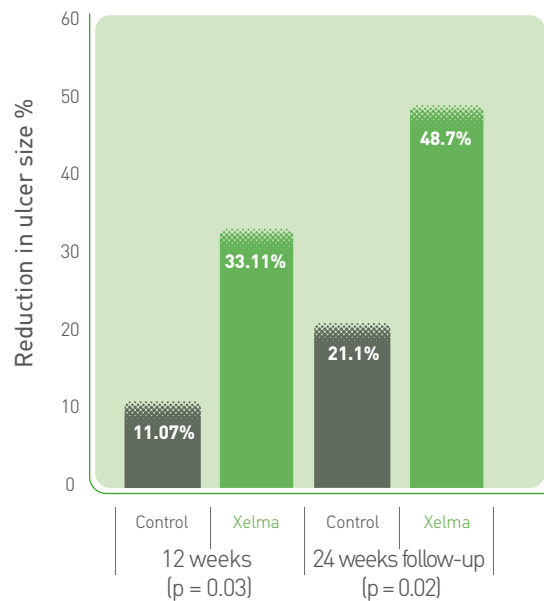
In a recent published randomised controlled trial, involving patients with hard-to-heal venous leg ulcers, patients were treated with either Xelma with compression therapy (n=42) or compression therapy alone (n=41) for up to twelve weeks.³

- 47.5% of those wounds in the Xelma group experienced a wound size reduction of more than 50%, compared with only 19.5% treated with compression therapy alone.³

12 weeks after treatment, the following results were achieved:

- The Xelma group continued to show a significantly greater wound size reduction (48.7%) compared with the control group (21.1%).⁴
- Patients treated with Xelma reported less pain between visits and at dressing changes, and their wounds showed lower exudation levels compared to those treated with compression alone.⁴
- The advanced amelogenin treatment should be viewed as a cost-effective treatment for venous leg ulcers.⁴

Reduction in ulcer size – Xelma plus high compression versus high compression therapy alone (control)⁴



The Xelma group showed a statistically significant threefold reduction in wound size, compared with the control group after twelve weeks of treatment³



Indicated for diabetic foot ulcers

As a result of the neurologic and vascular complications associated with diabetes, 12-25% of patients with this disorder develop foot ulcers.⁵

Diabetic foot ulcers (DFUs) have a negative effect on patient quality of life. They can lead to amputation and are associated with premature mortality. Unfortunately, a significant number of DFUs fail to respond to standard care (e.g. according to a recent review, approximately 70% of DFUs remain unhealed after 20 weeks of standard treatment).⁵

The complications arising from diabetic foot ulcers can also be costly in other ways. One recent study measured the monetary costs associated with DFU treatment. The results clearly proved that the cost of healing a DFU completely easily offsets the additional and much higher expenditures for extended hospital stays, antibiotics and surgery an unhealed DFU can necessitate.²

A separate study also showed DFUs to be more difficult to heal the longer they go untreated. The evidence supports early intervention as a key determinant for successful healing, justifying the initial treatment costs both from a fiscal and a quality of life perspective.⁶

Xelma has been shown to be effective in the treatment of DFUs:

- In a series of case studies involving 10 patients with either hard-to-heal venous leg ulcers (n=5) or DFUs (n=5) treated with weekly applications of Xelma for 12 weeks, 80% of the wounds changed from static to healing, indicating a beneficial effect of Xelma.⁷
- In a case study series involving 10 patients with non-healing DFUs, 80% of the wounds demonstrated a reduction in area and two completely healed during treatment with Xelma (weekly applications for up to 12 weeks).⁸
- In a case study series involving 3 patients with hard-to-heal DFUs, all wounds showed a positive response to treatment with weekly applications of Xelma, resulting in complete healing.⁹
- In a series of case studies involving 6 patients with hard-to-heal foot ulcers (diabetic, n=5; neuropathic, n=1), all wounds demonstrated a positive response to weekly applications of Xelma, with some wounds progressing to complete healing.¹⁰



How to use Xelma effectively

Xelma is a primary treatment for hard-to-heal wounds such as diabetic foot ulcers, venous leg ulcers and pressure ulcers. It restores the ECM by providing critical cell adhesion proteins.

Xelma is a sterile ready-to-use product for topical application. It is easy to handle and is applied once a week.

All wounds need key interventions to facilitate healing. If these have been attended to and the wound has not healed it is then appropriate to consider Xelma.

Maintaining the standard of wound care

To succeed with advanced treatments, it is important to maintain good standard care. Infection control, exudate management and wound bed preparation are essential. In the care of diabetic foot ulcers, off loading, glycemic control, infection control, treatment of oedema are essential. In the care of venous leg ulcers, high compression therapy is essential.

Instructions for use

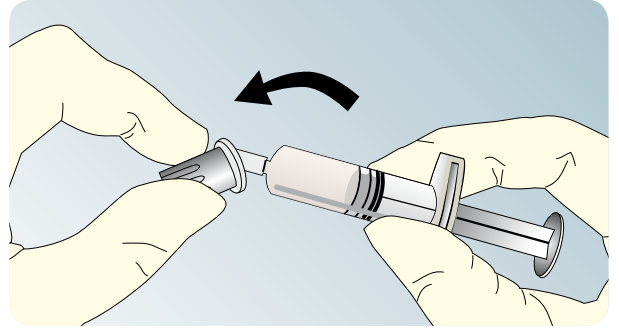
Area of use: Xelma is indicated for hard-to-heal wounds without clinical signs of infection, e.g. venous leg ulcers, diabetic foot ulcers and pressure ulcers.

Application: Xelma is intended for topical application, once weekly, and should be covered by a secondary dressing such as Mepitel®, Mepilex® or Mepilex® Border. If no improvement is observed within 6 weeks the treatment should be reassessed.

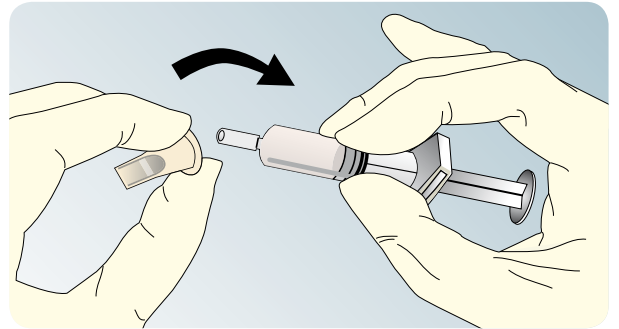
Precautions: Xelma should not be applied to infected wounds or until excessive exudate is controlled. Necrotic tissue, fibrin or slough should be removed before initiating the treatment. The syringe and applicators are single use items. Do not re-sterilise or reuse syringe or applicators. Do not use if sterile package is opened or damaged. Do not use after the expiration date.

Warning: Xelma must never be used for injection.

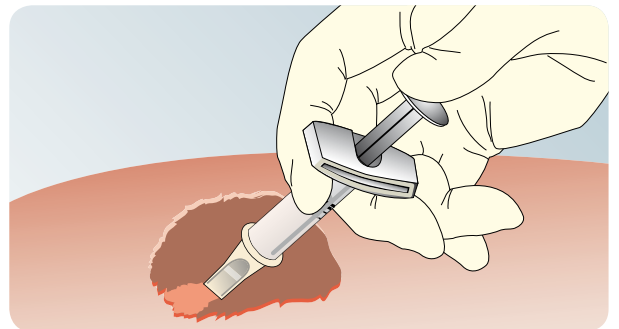
Storage: The product is stored refrigerated at (2–8°C).



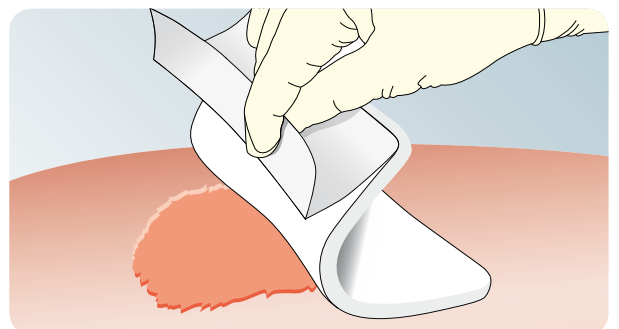
Measure wound area prior to use. Cleanse the wound as normal. Remove the rubber cap of the syringe.



Attach the silicone applicator for easy application. Ensure the product is not cold when applied to the wound.



Carefully apply a thin layer of Xelma over the wound area. The single use syringe is equipped with a scale related to wound size for guidance (0,5 ml = 10 cm² and 1 ml = 20 cm²).



Cover wound with secondary dressing, e.g. Mepitel, Mepilex or Mepilex Border. Depending on exudate level, the secondary dressing can be changed in between applications.

Remember off loading.



Assortment

	Art. No	Size	Pcs/shelf cont.	Pcs/transp. cont	Wound area coverage
New →	373727	0.5 ml	1 syringe	6 syringes	10 cm ²
	373737	1 ml	1 syringe	6 syringes	20 cm ²

Now available in a new smaller size for more precise application that minimises treatment costs of smaller wounds.

www.xelma.com

References

1. Schultz GS, et al. Wound Repair Regen 2003;11 (1 Suppl):S1-S28
2. Ragnarson Tennvall G, Hjelmgren J. Wound Repair Regen 2005;13 (1):13-8
3. Vowden P, et al. J Wound Care 2007;16 (5):189-95
4. Romanelli M, et al. J Wound Care 2008;17 (1):17-23
5. White R, McIntosh C. J Wound Care 2008 Oct;17 (10):426, 428-32
6. Margolis et al. Am J Med. 2003; 115:627-631
7. Meuleneire F. Poster presentation at the Symposium on Advanced Wound Care, Tampa, USA, 2007
8. McCardle J et al. Diabetic Foot J 2009;12 (1):27-32
9. Richards K, Chadwick P. Poster presentation at Wounds UK conference, Harrogate, United Kingdom, 2008
10. Vowden K, D'Arcy A. Poster presentation at the 3rd Congress of the World Union of Wound Healing Societies, Toronto, Canada, 2008

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