



A Simple Solution For Leg Ulcer Care



**Simpler Wound Management,
Without Compromise**

Leg Ulcer Burden - a growing problem



According to Guest et al in total, there were 1 million ulcers of the lower limb, which equates to 2% of the adult population having a lower limb ulcer in the study year¹⁴



Only 16% of all those with a leg or foot ulcer had a Doppler ankle brachial pressure index (ABPI) recorded¹⁴

59%

An estimated 59% of chronic wounds healed if there was no evidence of infection¹⁴



The annual NHS cost of managing wounds is estimated to be £8.3 billion pounds¹⁴

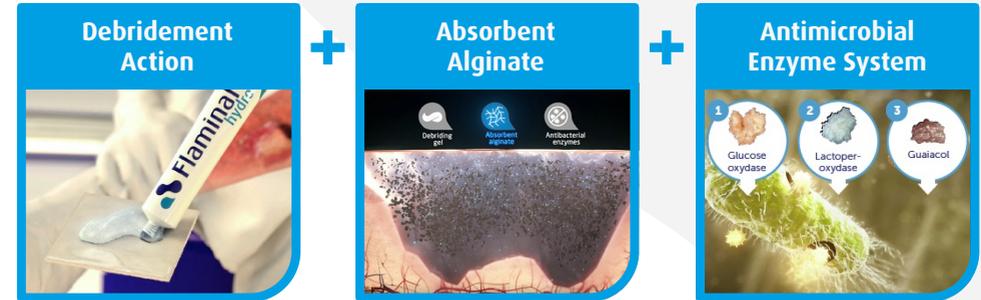


The National Wound Care Strategy recommendations for lower limb advises that when appropriate, people with leg and foot wounds should be supported to self-care¹⁵



Patient education helps patients to adhere to their treatment and can increase confidence to take on additional components of management²

What is Flaminal®?



A versatile, unique dressing designed to simplify leg ulcer wound management

- ✓ Speeds up the healing time^{1,9}
- ✓ Manages moisture balance⁴
- ✓ Continuously debrides the wound^{4,5}
- ✓ Reduces bacteria released from biofilm^{3,6*}
- ✓ Helps minimise patients' pain and discomfort^{9,10}
- ✓ Non-cytotoxic³
- ✓ Comfortable & easy to apply even in the most difficult areas^{5,7}
- ✓ Can be used throughout all stages of the healing trajectory⁵
- ✓ Better scar quality¹
- ✓ Reduces wound odour caused by bacteria^{5,8}

* Bacteria are absorbed into the Flaminal® gel structure and killed



Flaminal® - Improving outcomes in Leg Ulcers¹¹

Flaminal® in the management of Bilateral ulceration caused by Cutaneous Vasculitis¹¹

Day 1

Day 10

6 Months



Patient:

- 48 year old woman
- 10 month history of bilateral circumferential ulceration caused by cutaneous vasculitis

Treatment aims:

- Reduce wound bioburden (Staphylococcus Aureus)
- Debride slough
- Manage exudate
- Prevent peri wound maceration
- Control pain
- Prevent hospital admission

Treatment:

- Flaminal® Forte
- Non adherent secondary dressing
- Covered with super absorbent dressings
- Compression bandaging
- Dressing changes 3X a week in outpatient clinic

Results & Outcome

- Within 10 days fibrous slough was liquifying and autolytically debriding, which continued over next 5 months
- The peri wound skin improved as the bioburden and exudate levels reduced
- Pain was controlled and she felt she regained her quality of life

Flaminal®: Reduction in Bioburden & Biofilms¹²

Antimicrobial agent	Type	Biofilm efficacy	Guidance for use
Enzyme alginate gel	Alginate gel with two enzymes: ■ Lactoperoxidase ■ Glucose oxidase	<ul style="list-style-type: none"> ■ Prevents formation of biofilms at concentration MO.5% (w/v)^{12,13} ■ Inhibits growth of established biofilms at higher concentrations 	<ul style="list-style-type: none"> ■ Concentrations of alginate of 3% and 5% depending on level of exudate^{12,13}



Flaminal® Optimal Wound Healing -The Evidence



DEFEND

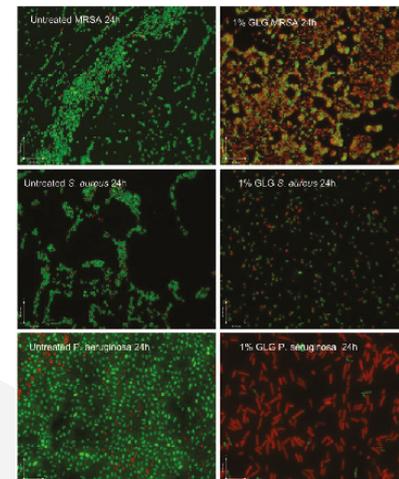
GLG-enzyme system combines effective control of microbial bioburden with non-cytotoxicity³

Effects of GLG enzymes system on 12 strains of Gram + and Gram - bacteria

- Successful in killing wide range of antibiotic-resistant bacterial strains
- Killed in 6 hours of incubation or less in vitro

Gram	Bacteria	Killed within 6 hours
+	Staphylococcus aureus (MRSA)	✓
	Enterococcus faecium	✓
	Enterococcus faecalis	✓
-	Escherichia coli	✓
	Klebsiella oxytoca	✓
	Enterobacter cloacae	✓
	Enterobacter aerogenes	✓
	Burkholderia multivorans	✓
	Pseudomonas aeruginosa	✓
	Stenotrophomonas maltophilia	✓
	Pandoraea apista	✓
	Achromobacter denitrificans	✓

Flaminal® can prevent formation of biofilms and inhibit established biofilms in vitro⁶



Effects of GLG enzyme system on biofilms of Staphylococcus aureus, methicillin-resistant S.Aureus and Pseudomonas aeruginosa

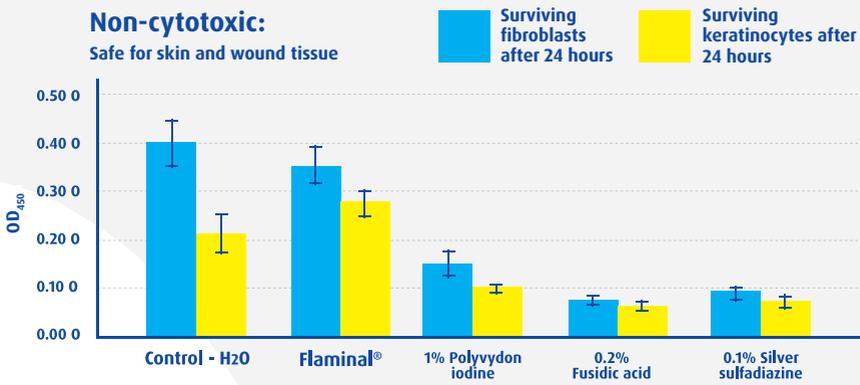
- Antibacterial component in Flaminal® can prevent the formation of biofilms and inhibit established biofilms in vitro (green=living biofilm, red=dead biofilm)



PROTECT

Flaminal® safe for skin and wound tissue³

Non-cytotoxic:
Safe for skin and wound tissue



Effects of GLG enzyme system on keratinocytes and fibroblasts

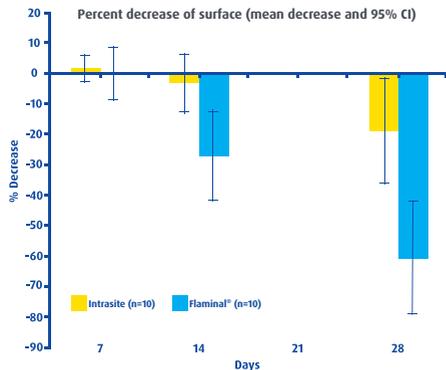
- Flaminal® significantly higher cell survival compared to other dressings in vitro
- Flaminal® shown to be non-cytotoxic.

IMPROVE

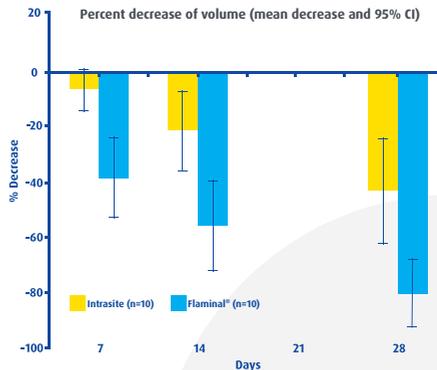
Flaminal® reduces wound size and volume over 28 days in chronic leg ulcers¹³

Comparing healing properties of Flaminal® vs Intrasite® on chronic leg ulcers over 28 days with two parallel groups of 10 patients

- Reduction of wound surface and wound volume were superior with Flaminal®



A significant difference is observed at day 14 and at day 28 (P < 0.01)



A significant difference is observed at day 7 (P < 0.001), day 14 (P < 0.001) and day 28 (P < 0.01)

Flaminal® Hydro or Forte - Which one should I use?



Perform wound cleansing and debridement techniques as per local/national guidelines

How wet is the wound? Consider the moisture balance - does it need moisture adding or moisture absorbing?

Slight to moderate exudate

FLAMINAL® HYDRO
3.5% Alginate

Moderate to heavy exudate

FLAMINAL® FORTE
5.5% Alginate

Apply Flaminal®
Cover the wound with a sufficiently thick layer (0.5cm)



Apply with a nozzle



Apply with a spatula



Apply with a syringe



Direct from the tube

Cover with your choice of dressing. This depends on the amount of exudate.

Change the dressing if exudate strikes through and check the status of the ulcer regularly for deterioration. Flaminal® can remain in place as long as the gel structure is intact (1 to 4 days).

Ordering Information



PACK SIZE	PIP CODE	NHS CAT NO.
5 x 15g tubes	324-2971	ELG021
1 x 50g tube	344-9600	ELG025
500g tub	-	ELG029



PACK SIZE	PIP CODE	NHS CAT NO.
5 x 15g tubes	324-2963	ELG022
1 x 50g tube	344-9592	ELG023
500g tub	-	ELG028

Once opened, and if recapped carefully, a tube of Flaminal® (Hydro or Forte) can be stored at room temperature and used for 12 months. A jar of Flaminal® (Hydro or Forte) 500 g however can be used for one week after its first opening. A pack of Flaminal® (Hydro or Forte) will be used for one patient only (multiple use - single patient).

Advice leaflets are a valuable tool that can build on the interaction between a clinician and the individual with the leg ulcer. An advice sheet that incorporates a self-help section can aid the person with the ulcer in their self care¹⁶

Please contact your local representative or info@flenhealth.com for further information on our Flaminal® leg ulcer shared care guide for patients.



References;

1. Hoeksema, H. et al. A comparative study of 1% silver sulphadiazine (Flammazine) versus an enzyme alginate (Flaminal) in the treatment of partial thickness burns. *Burns* 39 (2013) 1234-1241
2. Wounds UK. Best Practice Statement: Holistic management of venous leg ulceration. London: Wounds UK. Available to download from: www.wounds-uk.com
3. De Smet, K. et al. Pre-clinical evaluation of a new antimicrobial enzyme for the control of wound bioburden. *Wounds*. 2009;21:65-73
4. White, R. Flaminal a novel approach to wound bioburden. *Wounds UK*. 2006;2: 64-69
5. Jones & Oates 2018. TIME to assess wounds – a clinical evaluation of Flaminal Wounds UK | Vol 14 | No 3. Pages 63-69
6. Cooper, RA. Inhibition of biofilms by glucose oxidase, lactoperoxidase and guaiacol: the active antibacterial component in an enzyme alginate. *Int Wound J*. 2013;10:630-637
7. Beele et al 2012 Expert Consensus on a new enzyme alginate . *Wounds UK* 2012, Vol 8, No 1 pages 64-73
8. Flaminal IFU
9. Flaminal; A Clinical Trial to assess the efficacy of use in Partial Thickness Burns Mr Peter Campbell OAM, CNC Burns/Plastics- Royal North Shore Hospital Sydney, 2009, (poster presentation)
10. Flaminal Forte: Does it have a role in the management of acute burns, Mr Peter Campbell OAM, Ms Diana Van Der Saag, Dr Anna Loch-Wilkinson, Dr John Vandervord. Royal North Shore Hospital Sydney. Australian & New Zealand Burn Association ANZBA 2011, (poster presentation)
11. Jeanette King. The Management of a patient with bilateral ulceration caused by cutaneous vasculitis. Salford Royal NHS Foundation Trust support by Flen Health FH-CS-035
12. International Wound Infection Institute (IWII) Wound infection in clinical practice. *Wounds International* 2016
13. de la Brassinse, M. et al. A novel method of comparing the healing properties of two hydrogels in chronic leg ulcers. *J Eur Acad Dermatol Venereol*. 2006;20:131-135.
14. Guest JF, Fuller GW, Yowden P. Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013. *BMJ Open* 2020;10:e045253. doi:10.1136/bmjopen-2020-045253
15. National Wound Care Strategy Programme- Lower Limb Recommendations 2020 <https://www.ahsnnetwork.com/app/uploads/2020/11/Lower-Limb-Recommendations-20Nov20.pdf>
16. Wilson M., (2013) The leg ulcer: a shared approach. *Wound Essentials* 2013, Vol 8 No 1 p32-35