

Advice on the use of Stimulan[®]



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Version control

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V.1	Publication of guidance	December 2025	Created by Medicines and Medical Devices Committee, ratified by Clinical Senate.

Advice on the use of Stimulan[®]

Stimulan[®] (calcium sulfate) is a medicinal device licensed for use in the UK.

It is recognised that Stimulan[®], when prepared with appropriate antibiotics, is efficacious in the management of infected ulceration involving soft tissue and bone within the foot and its associated structures (Chon et al 2020; Widnall et al 2019; Arissol & Newsholme, 2024; Ragghianti et al 2023; Kavarthapu & Budair, 2021).

In addition, we note that some members who are involved in multi-disciplinary lower limb wound care clinics, may be involved in using Stimulan[®] in ulcers elsewhere in the lower limb.

The manufacturer's printed 'Instructions For Use' lists peripheral arterial disease (PAD) and uncontrolled diabetes as contraindications for the use of Stimulan[®]. However, the body of evidence from both the UK and the international community now supports its use in these patient groups when the specified antibiotics are used (Chon et al 2020; Widnall et al 2019; Arissol & Newsholme, 2024; Ragghianti et al 2023; Kavarthapu & Budair, 2021; Phyo et al 2021; Thankappan et al 2023). In this situation Members should be aware that Stimulan[®] is being used outside of its medicinal product license and is therefore 'off label' use.

We note therefore that the manufacturer's clinical advice, which supports the use of Stimulan[®] in these areas of practice, is now contrary to its printed advice provided in the packs. The printed literature is therefore in need of review and should not limit current safe and effective practice. This issue has been raised with the manufacturer for their consideration by clinicians both within and outside podiatry.

Care must always be taken to ensure that all other listed contraindications to Stimulan[®], identified in the manufacturers documentation, are taken into consideration in addition to any relating to the prescribed antibiotics added to Stimulan[®] when formulating and using the beads.

Stimulan[®] is licensed for use with the following antibiotics:

- Gentamicin
- Vancomycin
- Tobramycin.

There is a large body of evidence to support the use of Stimulan[®] using these antibiotics either singularly or in combination, with Gentamicin and Vancomycin being commonly used in combination with both good efficacy and safety (Widnall et al 2019; Arissol & Newsholme, 2024; Genovese et al 2016). When used in combination or with alternative antibiotics, members should be aware that Stimulan[®] is being used outside of its medicinal product license and is therefore 'off label' use. Microbiological findings should also be noted when deciding on the appropriate antibiotics for the individual case.

Members must also consider the concurrent use of oral or IV administered antibiotics in addition to those administered locally at the site of infection in Stimulan[®].

Non-medical prescribers can order Stimulan[®] and prescribe the appropriate antibiotics. This method requires the podiatrist or competent clinician to prepare the antibiotic into Stimulan[®] just prior to its implantation.

Members should note that the antibiotics used in association with Stimulan[®] must be made up specifically for each case on the day of use. This requires the podiatrist or competent clinician to prepare the antibiotic into Stimulan[®] just prior to its implantation.



Stimulan® beads prepared for each patient must be used at a specific appointment and must not be stored for use at a further appointment for the same patient at a later date because of the potential risks of contamination and degradation.

Packs of Stimulan® must be used on a 'one patient only' basis, they should not be split and used on more than one patient to reduce wastage as this is an infringement of prescribing regulations for the antibiotics concerned.

Stimulan® can only be ordered and prescribed as a "Special" by a medical prescriber. Specials are sterile packs of Stimulan® beads that come preloaded with antibiotics that are manufactured and sterile packed ready for use by a third party, independent of Biocomposites.

The Royal College of Podiatry encourages departments to produce their own standard operating procedures (SOPs) in the use of Stimulan® to support safe and effective prescribing based on microbiological evidence using the above advice as a foundation for good practice.

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