

# A clinical audit of Suprasorb® X+PHMB

Polyhexamethylene biguanide (PHMB) has been available as a wound irrigation fluid in Europe for some time. Recently, it has been successfully introduced into wound management within a range of dressings, including non-adherent products, gauze, drains, intravenous sponges and hydrogels. In some cases, the PHMB molecule has been chemically bound to the base material, providing it with antiseptic/antimicrobial properties when in contact with wound moisture. In other products, the active component is free to be delivered into the wound and periwound tissues, serving as a carrier for a wider antimicrobial activity by donating PHMB to the wound surface.

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## KEY WORDS

Suprasorb® X+PHMB  
Antimicrobial agent  
Moisture  
Bacteria

Moisture management and bacterial control are two of the fundamental issues in wound management. The new dressing, Suprasorb® X+PHMB (Activa Healthcare, an L&R Company) has been specifically designed to deal with these two issues simultaneously. Suprasorb X+PHMB is made up of a unique structure composed of biosynthetic HydroBalance fibres. These fibres are the products of a cellulose fermentation process using

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*Acetobacter xylinum*. The bacteria produce a mesh structure of cellulose fibrils which are 200 times finer than cotton, giving the material an exceptionally high surface area with enhanced moisture-handling capabilities and tensile strength. As a result of the biosynthetic HydroBalance fibres, the dressing is able to regulate the absorption and donation of moisture at

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the wound-dressing interface. Depending on the status of the wound, surplus exudate can be absorbed by the dressing, or moisture donated to provide an ideal moist wound healing environment.

This ability to balance moisture levels can occur within the same wound dressing, removing exudate from one area and donating moisture to others. In addition, the dressing contains the potent antimicrobial polyhexamethylene biguanide (PHMB) 0.3%. The PHMB component exerts its antimicrobial effects both within the

dressing and also at the wound-dressing interface. As the PHMB is not bound to the HydroBalance fibres of the dressing, it is released into the wound fluid along a concentration gradient. The presence of fluid in the dressing means that antimicrobial activity is possible, even on dry wounds (unlike dry antimicrobial dressings).

Mosti et al (2008) and Galitz et al (2009) found that the use of Suprasorb X+PHMB saw a decrease in patient-reported pain at dressing change. This was matched by a reduction of background pain following use. Galitz et al (2009) showed this to be significant ( $p < 0.05$ ) after the first day of use, and considered this to be a notable feature of the dressing's performance.

Suprasorb X+PHMB dressings are indicated for use on lightly to moderately exuding, superficial and deep, critically colonised and infected wounds in all stages of wound healing (Kingsley et al, 2009).

## What is PHMB?

The antiseptic PHMB is a mixture of polymers, structurally similar to the naturally-occurring antimicrobial peptides which support the innate immune response and protect against infection. While the precise action

of PHMB on bacteria is unclear; the primary targets appear to be the outer and cytoplasmic membranes of bacterial cells. PHMB adheres to bacterial cell membranes, causing them to leak potassium ions and other cytosolic components which results in cell death. There is evidence that once in the bacterial cell, PHMB also binds to DNA and other nucleic acids, damaging or inactivating them. As PHMB changes the bacterial cell membrane, once inside it cannot be removed by the bacterial defence system (Kingsley et al, 2009). PHMB is also effective at controlling fungal colonies (Shah, 2000; Lee et al, 2004), but does not adhere to healthy cell membranes and has shown no evidence of toxic effect on human cells (Ikeda et al, 1983; Moore and Gray, 2007).

#### Use of PHMB

PHMB has been in use as an antiseptic and disinfectant for approximately 60 years, with proven effectiveness against a broad number of bacterial and fungal species (Moore and Gray, 2007), and rapid and sustained action. It has been demonstrated to be effective at biofilm management with no evidence of bacterial resistance or systemic absorption. Comparative tests of PHMB's biocompatibility (the measurement of an antiseptic agent's activity in relation to its cytotoxicity) against other commonly used therapies to chlorhexidine, povidone-iodine, triclosan, silver and sulfadiazine (Müller and Kramer, 2008). Studies have shown that skin sensitising to PHMB is very low even in high concentration (Schnuch et al, 2000; 2007).

Recently, PHMB has been introduced into wound management within a range of wound care products. In some cases, the PHMB molecule is chemically bound to the base material, providing dressings with antimicrobial properties when in contact with wound moisture. These products protect against the development of wound infection by decreasing the bacterial load in the dressing and preventing bacterial ingress. In other products, the active component is

free to be delivered into the wound and periwound tissues; the dressing in this case being a carrier for a wider antimicrobial activity by donating PHMB to the wound environment.

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### **PHMB is indicated for the control of bacterial burden within wounds. Specifically, it is used to reduce bacterial burden in the critically colonised wound and may be indicated as infection prophylaxis in immunocompromised individuals.**

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PHMB has also been shown to have positive effects on wound healing. *In vitro* and *in vivo* studies have shown that PHMB:

- ▶▶ Reduces wound pain rapidly and effectively (Daeschlein et al, 2007; Galitz et al, 2009)
- ▶▶ Reduces wound odour (Daeschlein et al, 2007)
- ▶▶ Increases granulation tissue formation (Mueller and Krebsbach, 2008)
- ▶▶ Increases keratinocyte and fibroblast activity (Wiegand et al, 2008a)
- ▶▶ Reduces slough within the wound (Mueller and Krebsbach, 2008)
- ▶▶ Reduces MMP-induced periwound breakdown (Cazzaniga et al, 2002; Werthen et al, 2004)
- ▶▶ Assists in removing non-viable tissue (Kaehn, 2009).

PHMB is indicated for the control of bacterial burden within wounds. Specifically, it is used to reduce bacterial burden in the critically colonised wound and may be indicated as infection prophylaxis in immunocompromised individuals. Adjunct therapy with PHMB should also be considered to systemic treatment when treating serious wound sepsis. As with all topical antimicrobial therapies, if the wound is unchanged after ten days or deteriorates, alternative antimicrobial strategies should be considered (including systemic antibiotics). In most cases, treatment should not extend beyond

14 days unless previously agreed by a local specialist (Best Practice Statement, 2010).

PHMB's ability to effectively bind to proteins is a key feature of its success as an environmental disinfectant. In wound care, clinicians should choose wound care products which are appropriate to patient needs, be they as barriers to bacterial spread (preventing bacterial ingress or cross-contamination from colonised wounds), or as 'donating' dressings, which are also able to disperse PHMB into the wound.

In addition to wound dressings containing PHMB, wound irrigation fluid containing PHMB is also available, however, studies indicate that solution concentration should be between 0.01%–0.04% (depending on clinical need) (Dissemond et al, 2010), and contact between the bacterium and PHMB needs to be maintained for 10–15 minutes to ensure maximum antibacterial action. Continuous irrigation is possible, although clinicians need to be aware of the technical and practical issues that might arise, particularly in community settings.

The use of PHMB has specific contraindications. PHMB must not be used:

- ▶▶ For peritoneal lavage
- ▶▶ For antiseptic joint lavage (cartilage toxicity)
- ▶▶ In applications involving any part of the central nervous system (CNS), including the meninges and intralumbal applications
- ▶▶ For applications involving the middle or inner ear, or intraocular applications
- ▶▶ During the first four months of pregnancy (at any time thereafter, a strict benefit/risk assessment has to be performed)
- ▶▶ In patients allergic to PHMB (Dissemond et al, 2010).

As can be seen, apart from a very small minority of patients who fall within the last two groups, PHMB does not have any contraindications for application within the wound population.

### Health economics and cost-effectiveness

Cost-effectiveness of treatments has to be taken into account when implementing new therapies. Health economics assesses the cost of treatment implementation against measurable health gains, identifying where cost savings can be realised. Primary measures such as time to healing and frequency and cost of dressings and bandages need to be considered. Secondary factors, such as the use of pain control and reduction in healthcare interventions as wounds heal, should also be factored in. In the management of surgical site infection (SSI), the use of PHMB-based wound care products has been shown to have a marked impact on reducing infection rates and costs to healthcare providers (Gilliver, 2009). Although empirical evidence is currently unavailable, it would seem reasonable to conclude from the reduction in pain found in studies, the increased healing rates and effectiveness in bacterial management in leg ulcer care and in other situations, that PHMB offers a cost-effective form of treatment. It is predicted that such opinion will be supported by firm data in the near future.

The management of wounds has a potentially major impact on health economic assessment due to the high risk of infection in these wounds and the long-term impact on function. Failure to preserve function can adversely affect rehabilitation and return to normal activity, and may result in prolonged periods of healthcare interventions, corrective surgery and outcomes such as limb amputation.

In summary, PHMB has a number of properties and characteristics which make it particularly appropriate for use in critically colonised and locally infected acute and chronic wounds, namely:

- ▶ Proven broad antimicrobial action (Cazzaniga et al, 2002; Wright et al, 2003; Eberlein and Wild, 2008; Mosti et al, 2008; Müller and Kramer, 2008; Mueller and Krebsbach, 2008; Kaehn, 2009; Wild et al, 2009)
- ▶ Anti-fungal activity (Shah, 2000; Lee et al, 2004)
- ▶ Minimum blood/protein inactivation (reduction of effect on mucous membranes due to presence of mucin) (Ansorg et al, 2002)
- ▶ Sustained, post-application effect (Rosin et al, 2002)
- ▶ Established promotion of wound healing (depending on concentration) (Davies and Field, 1969; Kramer et al, 2004; Daeschlein et al, 2007; Wiegand et al, 2008a, b)
- ▶ Additional anti-inflammatory properties
- ▶ No development of resistance reported to date (Gilliver, 2009; Weigand et al, 2009)
- ▶ Reduction of biofilm (Harbs and Siebert, 2007) and fibrin (Körber et al, 2008)
- ▶ Good clinical safety (Disch et al, 2007; Mulder et al, 2007; Bruckner et al, 2008)
- ▶ Targeted action on bacterial cells (Ikeda et al, 1983; 1984)
- ▶ Biocompatibility index > 1 (Müller and Kramer, 2008)
- ▶ No known risks of adsorption (Kramer and Roth, 2008)
- ▶ No known toxic risks (Moore and Gray, 2007)
- ▶ Low risk of contact sensitisation (Schnuch et al, 2000; 2007).

PHMB offers a new method of bacterial control which has been proven safe, efficient and cost-effective. This will provide benefits to patients and clinicians in providing alternative and additional tools to manage bacterial burden within the wound care environment.

### Case report one

This case report focuses on an 80-year-old female patient admitted to secondary care suffering from a chest infection. On day two of her admission she sustained a trauma injury to the calf area of both legs from contact with the bed rails. The outcome was extensive haematoma formation.

The haematomas were assessed by the plastic surgeon on-call, and sharp debridement was performed on the ward, and a silver tulle dressing applied (Urgotul® SSD).



Figure 1. Partially debrided haematoma on right leg.



Figure 2. Suprasorb X+PHMB dressing in place.

Follow-up assessment was made by the tissue viability nurse two days later. The wounds were very painful and the patient was reluctant to lie on her side for the assessment and dressing change (Figure 1).

The patient's blood results revealed haemoglobin (Hb) 6.6 and C-reactive protein (CRP) 154. She suffered from diabetes which was controlled with oral hypoglycaemics, and had recently been treated for shingles and leg cellulites. She had a cardiac pacemaker *in situ* and was taking warfarin.

### Method

The right leg wound was physically debrided and cleansed with normal saline, and Suprasorb X+PHMB was applied to the wound and into the undermining areas (Figure 2). The patient was comfortable throughout the procedure, and a secondary foam dressing (Biatain®, Coloplast) was applied with a wool (Softban, Smith and Nephew) and crepe bandage toe-knee. The dressing was changed on alternate days.

The patient was reviewed on a Friday afternoon, but the tissue viability nurse was unable to access sufficient dressings to treat both leg wounds with Suprasorb



**Figure 3.** Right leg wound treated with Suprasorb X+PHMB had less undermining haematoma evident, and no surrounding erythema or wound malodour.



**Figure 4.** Left leg wound treated with silver tulle dressing. Haematoma drying out and malodorous.



**Figure 5.** Left leg wound with necrosis, erythema and oedema.

X+PHMB over the weekend. The decision was taken to continue to manage the left leg with silver tulle dressing, secondary foam dressing, wool and crepe.

#### Results

On Monday, the right leg wound

was healthier with less undermining haematoma evident, and no surrounding erythema or wound malodour (Figure 3). The dressing change was described as 'comfortable', however, she did complain of general aching in the legs at other times of the day. The patient had received a transfusion of a unit of blood and her Hb was now 9.0, however the CRP had increased to 259, although blood cultures were negative.

The left calf wound which had been managed with the silver tulle dressing was largely unchanged and the haematoma had started to become dry and malodorous (Figure 4). There was erythema and oedema at the margins and cleansing was painful (visual analogue score [VAS] 5). The patient's international normalised ratio (INR) was 3.2 and so sharp debridement was not considered at this stage, and the wound was redressed with the silver tulle dressing.

Necrosis, erythema and oedema persisted two days later in the left leg wound (Figure 5), and the patient was complaining of wound pain. The INR had reduced to 2.2 and a decision was taken by the tissue viability nurse to perform sharp debridement (Figure 6). Suprasorb X+PHMB was applied to the wound to continue the debridement process while controlling the bacterial bioburden.

In two days, following treatment with Suprasorb X+PHMB, the left leg wound had improved and there was also marked improvement in oedema and erythema in the surrounding tissues. The patient reported less pain at dressing change and also in between dressings (Figure 7). At this stage, the right leg wound which had been treated throughout with Suprasorb X+PHMB was fully debrided of haematoma, using a combination of Suprasorb X+PHMB and physical debridement, with no indication of local infection (Figure 8). The patient's medical condition had stabilised and she was safely transferred out of secondary care to continue her rehabilitation.

This case report demonstrates a safe debridement option for a patient



**Figure 6.** Left leg wound after sharp debridement.



**Figure 7.** Left leg wound after two days' treatment with Suprasorb X+PHMB.



**Figure 8.** Right leg wound at the same time as Figure 7, showing no indication of local infection.

with multiple comorbidities which increase the risk of systemic infection, and illustrates effective management of wound bacteria during the acute management phase.

#### Case report two

A 38-year-old female presented



**Figure 9.** An extensive burn colonised with MRSA in a HIV positive patient.



**Figure 10.** Suprasorb X+PHMB contouring well to the shoulder and upper back area.



**Figure 11.** The wound following 48 hours treatment with Suprasorb X+PHMB.

unconscious at the emergency care centre. The patient was an intravenous (IV) drug user and was both hepatitis C positive and human immunodeficiency virus (HIV) positive. She had collapsed at home following a drug overdose, sustaining a cerebral bleed and an extensive burn to her shoulder and upper back from a radiator. She was admitted to the neurosurgical high dependency unit.

#### Method

The patient was assessed by the plastic surgeons and prescribed topical silver sulfadiazine and tulle dressings daily. In view of her comorbidities, no sharp debridement was attempted in the high dependency unit. The wound became colonised with methicillin-resistant *Staphylococcus aureus* (MRSA) and the plastic surgeon referred the patient to the tissue viability nurse for ongoing wound management. This situation posed multiple wound management challenges, including wound infection, exudate management, odour control and cross-contamination of other vulnerable patients.

The wound dimensions were 26x15cm and 6x5cm. There was high exudate and malodour and, although the patient was ventilated, she was able to indicate that the wound was painful (Figure 9).

#### Results

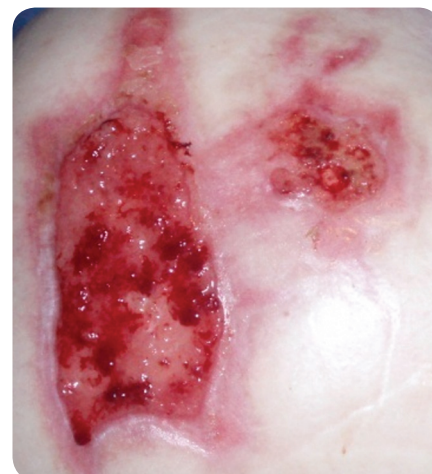
The wound was dressed with Suprasorb X+PHMB and a secondary adhesive foam dressing (Biatain adhesive, Coloplast). The dressing was changed on alternate days (Figure 10). The Suprasorb X+PHMB dressing was easy to apply and conformed well to the body.

After 48 hours there was significant improvement to the wound. A large area of necrosis had debrided and the wound bed appeared healthier. There was significantly less malodour and the periwound skin was healthy, despite high levels of exudate and overlapping of the wound margin with the moist dressing (Figure 11).

Following two further dressing changes, there was no malodour and the wound continued to debride. Epithelialisation was now evident at the wound margin, and wound cultures showed no significant growth. The patient's medical condition had stabilised and she was able to move to a ward area as she no longer needed to be isolated due to infection. This proved to be a turning point in her recovery, because she was now receiving more stimulation and



**Figure 12.** Significant debridement achieved and evidence of epithelialisation at the margins.



**Figure 13.** At four weeks there was no significant bacterial growth and the wound was progressing to healing.

interaction with others in the ward area (Figure 12).

After four weeks of treatment the wound had progressed significantly. The wound dimensions were 15x7cm and 3x3cm. There was no significant bacterial growth, no malodour and good progression to healing, and the patient was able to transfer to a rehabilitation unit for ongoing care (Figure 13).

#### Case report three

This case report features a 76-year-old male who presented to the tissue viability department with a large pressure ulcer on his sacrum. He was admitted to the intensive care unit having collapsed at home, where he lay overnight. The patient had a history

of cardiac disease, respiratory failure and sepsis.

On initial assessment, the patient was on artificial ventilation. The ulcer covered an area measuring 13x7cm and comprised red, hard non-blanching tissue with a central plug of black yellow tissue. The wound needed to clearly demarcate, in order to determine the extent of underlying tissue damage (Figure 14). As the ulcer was being reviewed immediately post trauma, the full extent and degree of tissue necrosis that would occur was still unclear. The team was also having difficulty maintaining any dressing regimen as the patient was incontinent of faeces.

**Assessment**

Over a period of five months, the patient's overall medical condition stabilised and improved. However, due to the extent of underlying tissue involvement, the ulcer debrided centrally, revealing a wound measuring 3.5x3x0.2cm. It presented as 100% granulation tissue, which was pale in colour and failed to respond to the treatment regimens being used (Figure 15). The decision was taken to start Suprasorb® X+PHMB, secured with a secondary foam dressing to absorb any excess exudate. It was hoped that the antimicrobial properties of Suprasorb X+PHMB would kick-start the healing phase and encourage the promotion of granulation tissue.

Over a period of two weeks, the dressing was changed every 3–4 days. On review, the wound dimensions had reduced slightly to 3.2x3x0.1cm, but of more clinical significance was the presence of friable red granular tissue (Figure 16), which was actively responding to treatment.

During this time, the patient was also diagnosed with *Clostridium difficile*, which he was being treated for. However, this led to an increased frequency of dressing changes and a number of episodes of wound contamination.

**Conclusion**

Over the 15 days of treatment with



Figure 14. Pressure damage has occurred but the wound still has to demarcate.

Suprasorb X+PHMB, the team saw the wound positively respond and develop healthy granulation tissue. The dimensions of the wound reduced slightly and the treatment also prevented any deterioration or infection developing in a wound that was frequently contaminated with faecal enzymes.

**Case report four**

This patient was a 68-year-old female with a history of bowel disease who presented with a dehiscenced laparotomy wound following the formation of a stoma. The wound was 28.5x2cm wide and 3cm deep, with a wound bed consisting of 30% sloughy tissue and 70% subcutaneous tissue. There was no infection evident and exudate was low in volume and viscosity. She was immediately started on topical negative therapy (TNP) using AMD gauze (Covidien). The dressing was changed every 48 hours (Figure 17). She continued with this regimen for eight weeks.

**Review**

On review, the wound was 26x2.5cm wide and 1.5cm deep and had a wound bed consisting of 100% granulation tissue. However, the wound appeared

to be critically colonised as no progress had occurred for the preceding two weeks (Figure 18).



Figure 15. Granulation tissue appears pale in nature and is not actively improving.



Figure 16. The wound developed red granular tissue.



Figure 17. Deep dehiscent surgical incision undergoing negative pressure wound therapy.



Figure 18. The granulation development and reduction in exudate indicate that the NPWT can be stopped.

The patient was also being discharged home from convalescence care and did not feel able to deal with the TNP system at home as she lived by herself. At this point, the patient's wound was managed using Silvercel® ribbon (Systagenix Wound Management) secured with an Alione Adhesive dressing (Coloplast), and was changed as exudate dictated.

The wound continued to be treated with topical antimicrobial agents for a number of weeks but started to show no signs of improvement. At the first treatment review after four weeks, the wound measured 13x2cm and was 1cm deep. The tissue present was 100% granulation, no infection was evident, and the exudate was of medium volume and viscosity (Figure 19). As the silver dressing had failed to produce consistent improvement, it was decided to switch the primary dressing to Suprasorb X+PHMB.

The patient presented to the clinic

two weeks later and the wound had reduced in size to measure 12x1.9cm and 0cm depth (Figure 20). The wound bed consisted of 100% granulation

### The ongoing treatment with Suprasorb X+PHMB re-balanced the wound, reducing the level of bacteria but allowing the wound to continue to heal.

tissue, exudate levels had increased and viscosity was low. There was odour present and a wound swab confirmed the existence of *Pseudomonas* infection.

Management with Suprasorb X+PHMB was continued, but due to the increased exudate volume, dressing changes became daily rather than every 2–3 days as before. Wound swabs identified the presence of MRSA and *Pseudomonas aeruginosa*. No



Figure 19. Static, non-healing wound with evidence of previous healing in the form of reduction in depth and epithelium at one margin.



Figure 20. In this image the wound has a thin layer of slough across its surface.



Figure 21. The wound has begun to epithelialise at the left margin and is contracting.

antibiotic therapy was started. When the wound was reviewed a week later, it had continued to improve and now measured 11x1.9cm and 0cm deep (Figure 21).

The wound remained granular, exudate had reduced in volume and the odour had gone. A swab was taken that showed no evidence of *P. aeruginosa* but MRSA was present. It was decided to continue with the current treatment regimen as it was providing positive clinical outcomes, the wound was only colonised with MRSA and no infection or critical colonisation was evident.

### Conclusion

The wound continued to be treated with Suprasorb X+PHMB and secured with Alione adhesive as the secondary dressing. Dressing frequency was reduced to alternate days. The results from this case would suggest that the wound had stopped healing due to the presence of bacteria critically colonising the wound. Suprasorb X+PHMB

Table 1

Suprasorb X+PHMB evaluation table

Sex	Age	Wound type	Location	Infection status at first review	Infection status at last review	Overall outcome of treatment, i.e. reduction in infection status, pain reduction, etc
Female (case 1)	80	Traumatic wound	Bilateral calves	Critically colonised	Colonised	Reduction in infection, reduction in pain, debridement of necrotic tissue
Female (case 2)	38	Burn	Shoulder	Critically colonised	Colonised	Reduction in infection, reduction in pain, reduction in wound size, debridement of necrotic tissue
Male (case 3)	76	Pressure ulcer	Sacrum	Critically colonised	Colonised	Reduction in infection
Female (case 4)	68	Surgical wound	Abdomen	Critically colonised	Colonised	Reduction in infection, reduction in wound size
Male (case 5)	80	Leg ulcer	Lower left leg	Local infection	Colonised	Reduction in infection, reduction in pain
Female (case 6)	78	Open leg wound	Left lower leg	Colonised with infected surrounding area	Colonised	Effective prophylaxis against real risk of infection
Female (case 7)	18	Traumatic wound	Right foot	Critically colonised	Colonised	Reduction in infection, reduction in pain
Male (case 8)	64	Surgical wound	Abdomen	No infection	No infection	Wound healing encouraged, reduced exudate, increased granulation tissue
Female (case 9)	87	Leg ulceration	Lower left leg	Critically colonised	No infection	Reduction in infection, reduction in pain, increased epithelialisation
Male (case 10)	55	leg ulcer	Lower right leg	Critically colonised	Colonised	Reduction in infection, reduction in pain, increased epithelialisation

appeared to kick start the wound into healing and was effective in managing the development of a local infection and facilitating healing.

The ongoing treatment with Suprasorb X+PHMB re-balanced the wound, reducing the level of bacteria but allowing the wound to continue to heal.

### Summary

Table 1 summarises patient details, wound types and clinical outcomes from a patient cohort of 10 across two sites. The patients were recruited from referrals made to the tissue viability departments on both sites. Suprasorb X+PHMB not only absorbs exudate, but can also manage wound moisture. The

product is adaptable and can deliver a clinically-proven, effective antimicrobial source to the wound bed, enabling clinicians to balance bacterial load as well as providing the optimum wound environment for tissue repair. **WUK**

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## Key points

- ▶▶ Suprasorb X+PHMB is made up of a unique structure composed of biosynthetic HydroBalance fibres.
- ▶▶ Cost-effectiveness of treatments has to be considered when implementing new therapies.
- ▶▶ PHMB offers a new method of bacterial control which has been proven safe, efficient and cost-effective.
- ▶▶ Suprasorb X+PHMB not only absorbs exudate, but can also donate moisture to a wound depending on the wound conditions and requirements.

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