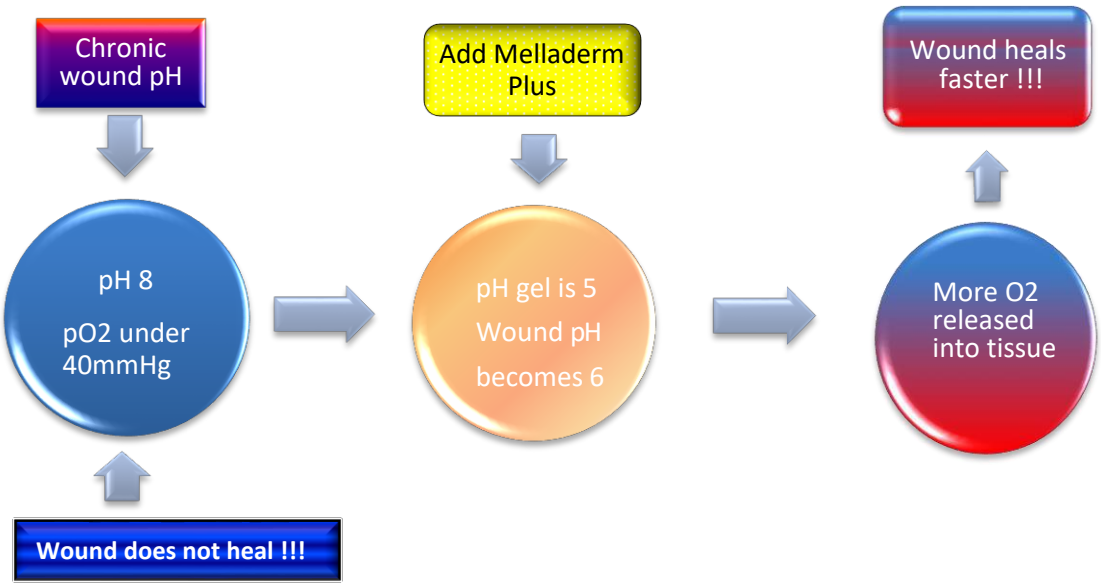
Sanoskin® Meladerm PLUS Wound Gel

Overview

- A unique natural medical grade honey-based gel
- Patented sterilisation process – the honey is neither heated nor irradiated, but **ozonated** [i]
- Inhibits the growth of Staphylococcus Aureus, including Methicillin-Resistant Staphylococcus Aureus (MRSA), Pseudomonas Aeruginosa and Candida Albicans [ii]
- Has debriding capabilities, does not adhere to the wound and it can stay up to 48 hours [iii, iv]
- This medical grade honey can be diluted 30 times before losing its antibacterial effect [iii]



Product description

SanoSkin® Melladerm PLUS is designed specifically for the patients with necrotic or sloughy wounds. This medical grade honey can be diluted 30 times before losing its antibacterial effect[iii]. When the gel is in contact with the wound, due to the high sugar content of honey, fluid is extracted from the surrounding tissue. The osmotic action creates a moist wound-healing environment and together with the honey stimulates the wound healing process, facilitates autolysis and promotes epithelial migration[v]. The gel dilutes gradually and can be removed easily with a wound cleanser, if required. Melladerm PLUS is a primary wound dressing that can be covered by most commonly used secondary dressings.

During its processing into a wound gel this honey is not heated or irradiated because this is known to destroy the honey healing properties. The Bulgarian honey has a very high peroxide level (strong antiseptic) and is sterilized by the SanoMed Manufacturing bv patented method (ozonation). Melladerm PLUS can be used to fill the wound cavity and then covered with a secondary dressing. The gel is easy to apply and will not adhere to the wound. Melladerm PLUS has debriding capabilities and has unique healing properties.

Specifications

Brand	SanoSkin® Melladerm PLUS
Process	Ozonation (Honey)
Delivery System	Tube
Department	Dermatology, Intensive Care unit, Oncology, Wound Care/Management
Product Type	Gel
Ingredients	Ozonated honey, Propylene glycol, PEG 4000
Sting (pain sensation)	Low to no-sting on application
Volume (gr)	20gr and 50gr
Contra-indications	Do not use on individuals with a known sensitivity to honey or bee products

Indications

- Superficial chronic wounds – bed sores, pressure ulcers, leg ulcers, diabetic foot ulcers, sloughy wounds, fungating wounds (deodorizing and debriding)
- Contaminated acute wounds – surgical wounds (postoperative wounds), traumatic wounds (superficial wounds, cuts) small burns and laser wounds (1st and 2nd degree)
- Abrasions
- Necrotic wounds
- Malodorous wounds
- Donor and recipient graft sites

Contraindications

Do not use on individuals with a known sensitivity to honey or bee products.

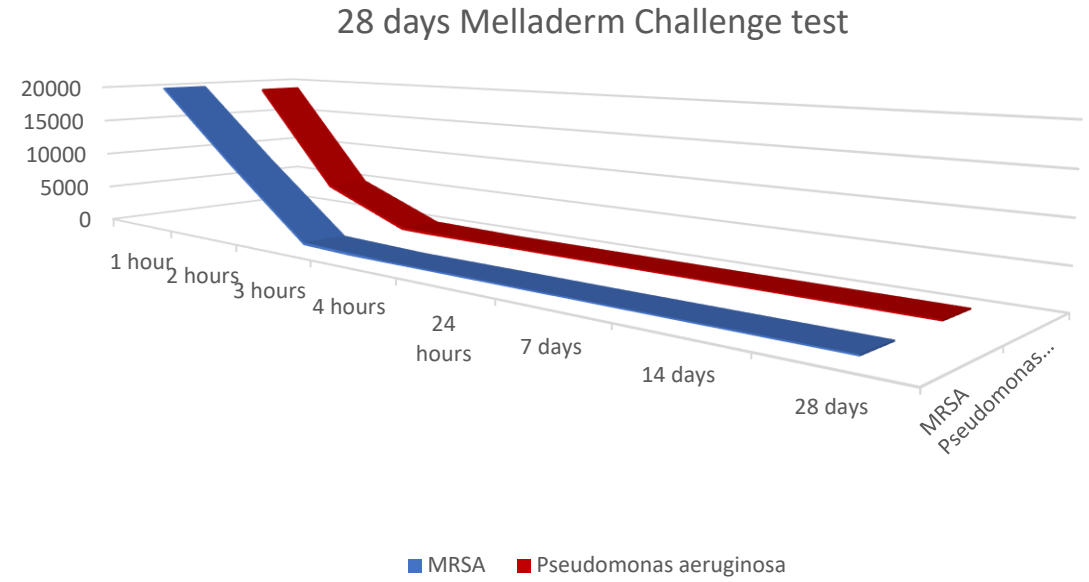
Precautions and Observations

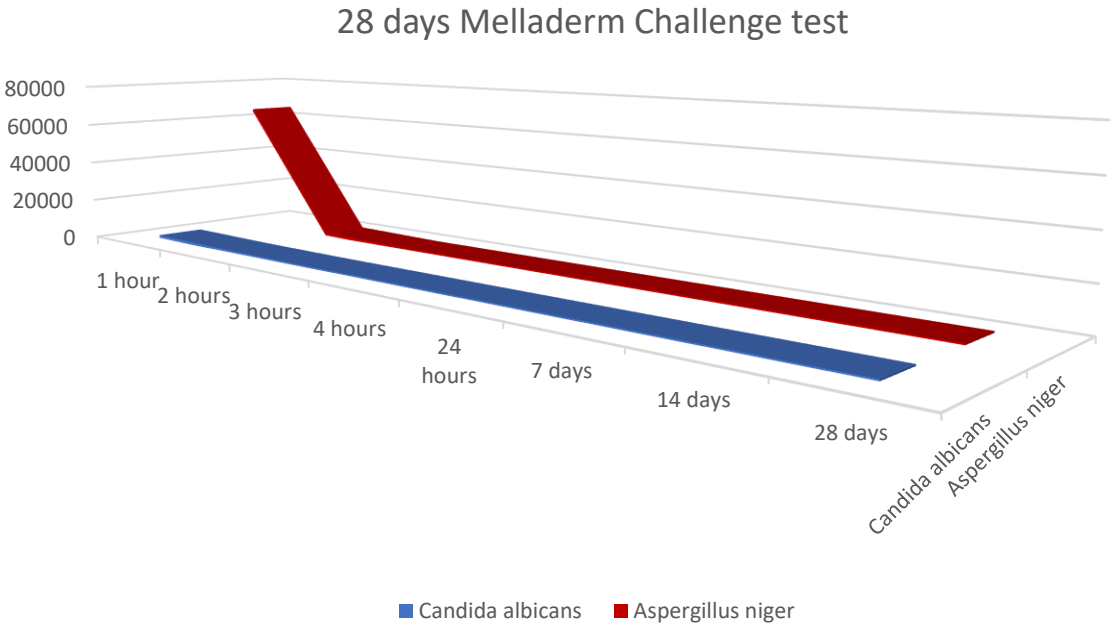
- Product contains honey, PEG 4000, glycerin and polyethylene glycol
- If necessary, consult a healthcare professional for the appropriate medical treatment
- Inspect and clean the wounds with a SanoSkin® cleanser
- Bacterial colonisation of chronic wounds is always present and is not a contraindication for using SanoSkin® Melladerm PLUS
- Due to autolytic debridement the wound may appear deeper after the first dressing change
- SanoSkin® Melladerm PLUS is for single patient use only
- Seek medical supervision if signs of infection occur
- Consult a healthcare professional for the appropriate medical treatment when appropriate

Efficacy Test (PET)

All test results show that the most common wound bacteria will be killed within 24 - 48hrs. Results in vivo corroborate with these test results and wounds will be free from most bacteria (after treatment), including MRSA and VRE bacteria. Consequently, most wounds heal faster. All honey products antibacterial properties are tested with a PET test. We show here only the results of Melladerm PLUS. A PET or challenge test is a European Pharmacopeia test that is used to check the antibacterial activity of a topical preparation over a period of 28 days (continuously). The ointment is inoculated with a high number of micro-organisms and then re-cultured at specific times. A log reduction of 3 is required in 7 days. As can be seen in the table hereunder the amount of St. Aureus starts at 1,9 x 106 and falls quickly to 0,4 x 102 which is a log reduction of 5 instantly and this effect lasts for the duration of the PET test. This means that the Melladerm PLUS is killing micro-organisms the moment the wound dressing is in contact with the moist wound and keeps killing bacteria over a long period.

CFU (colony forming units)	1 hour	2 hours	3 hours	4 hours	24 hours	7 days	14 days	28 days
MRSA	20000	9900	400	40	30	0	0	0
Pseudomonas aeruginosa	19000	5000	260	30	20	0	0	0
Candida albicans	1050	300	30	10	0	0	0	0
Aspergillus niger	65000	1000	40	20	0	0	0	0





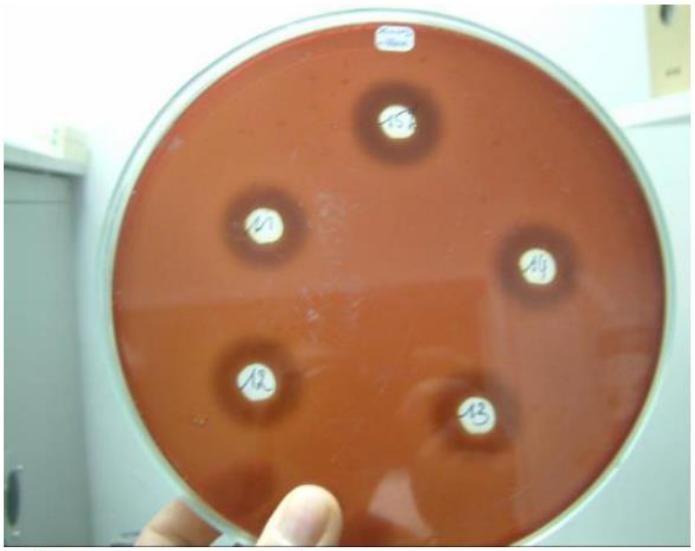
Zone of Inhibition test

A zone of inhibition test was performed showing that Melladerm® Plus could be diluted 30 times before losing its antibacterial activity against Staphylococcus aureus. To execute the actual assay, we choose an LMG-reference culture, i.e. Staphylococcus aureus subsp. aureus Rosenbach 1884 AL. The test strain is cultivated in TBS (Triple Sugar Broth), incubated at 35°C for 24h. By means of pour-plate method the concentration of the overnight culture is determined (1x109 cfu/ml). A 1000 fold dilution of this overnight culture in sterile physiological water gives us a homogeneous suspension with a concentration of 1x106 cfu/ml. 1,0ml of this suspension is added to 100ml of an appropriate medium (Colombia-agar +5% sheep blood) and gives an end concentration of 1x104 cfu/ml. The inoculated medium is now ready to be poured in glass petri-dishes, 19cm of diameter, per 100ml. When the medium is solid, pierce 5 holes (Ø 13,8mm) on each plate. A serial dilution of the SanoSkin® Melladerm® Plus gel is prepared in sterile distilled water. A 20% (m/v%) stock solution of the gel is prepared in sterile distilled water. Starting from this solution, the following dilutions are made: 20% -19% - 18% - … 2% - 1% m/v. From each dilution 200µl is transferred into the prepared wells in the plates. As mentioned before, 5 dilutions per plate.

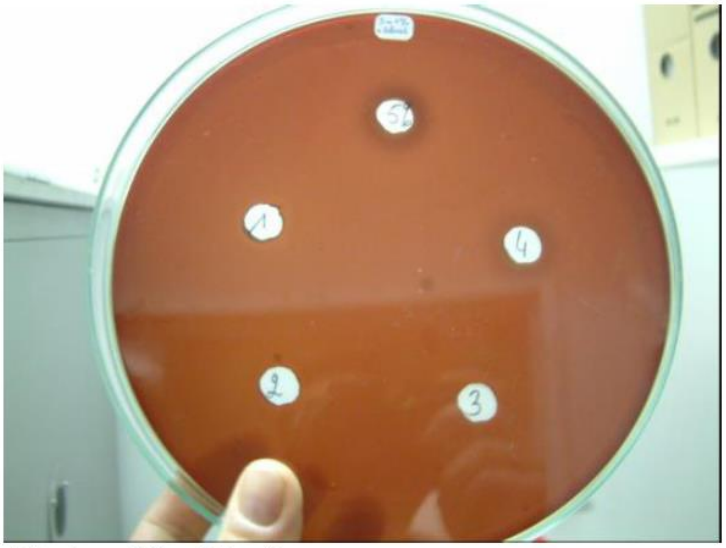
Due to the β-haemolytic activity of the used strand of Staphylococcus aureus, it is rather easy to detect the inhibition zones (the darker, brownish circles around the pierced wells, see pictures below.

Obviously, we can conclude that SanoSkin® Melladerm Plus inhibits the growth of Staphylococcus aureus when the concentration of the product is higher than 4% m/v.

This clearly demonstrates the effect of the hydrogen peroxide activity of the honey.



Dilutions 15% - 11% m/v.



Dilutions 5% - 1% m/v

Legal Disclaimer

SanoSkin® Melladerm Plus is a medical device listed on the Therapeutic Goods Register, ARTG ID: 317491. The information provided on the SanoMed website is true and correct; however, it does not supersede advice from a healthcare practitioner. It is essential that you read the Instructions for Use document (IFU can be found inside each box) prior to using any SanoMed product. Seek advice from a healthcare practitioner. If the condition deteriorates, discontinue use.

References

[i] Vandeputte, J. (2013). U.S. Patent No. 8,425,942. Washington, DC: U.S. Patent and Trademark Office.

[ii] Data on file

[iii] Nestjones, D., & Vandeputte, J. (2012). CLINICAL EVALUATION OF MELLADERM PLUS: A HONEY-BASED WOUND GEL. Wounds UK, 8(2).

[iv] Gethin, G., Cowman, S., & Kolbach, D. N. (2015). Debridement for venous leg ulcers. Cochrane Database of Systematic Reviews, (9).

[v] Winter, G. D. (1962). Formation of the scab and the rate of epithelization of superficial wounds in the skin of the young domestic pig. Nature, 193(4812), 293-294.

If you would like to find out more or request samples, please contact:

Argyris Giantsis
Director of SanoMed Australia
PO Box 479, Surry Hills, 2010, NSW, Australia
T: 1300 757 034
E: info@sanomed.com.au
W: www.sanomed.com.au