

BURNAID®

WHAT IS Burnaid AND HOW DOES IT WORK?

The Burnaid range consists of sterile gel impregnated burn dressings and sachets and tubes of gel, for the immediate first aid treatment of burns. Burnaid rapidly cools the burn helping to prevent further tissue damage and aid the healing process, and offers the patient rapid and ongoing pain relief.

Burnaid Gel consists of in excess of 90% water trapped in a proprietary gel, containing a small percentage of Melaleuca Oil – a naturally occurring substance, steam distilled from the leaves of the Australian Melaleuca alternifolia tree. Melaleuca Oil is a proven antiseptic, which exhibits local anaesthetic and anti-inflammatory properties.

The Burnaid Dressing consists of a 3mm thick pad of open cell foam impregnated with the Burnaid gel. When placed on a burn, a 3mm layer of gel is held on the skin.

From the patient's perspective, they are afforded almost immediate pain relief from the cooling gel and the anaesthetic properties of the Melaleuca Oil. The cooling properties of the dressing helps to halt the burn progression and minimise further tissue damage. Furthermore being in excess of 90% water, the Dressing re-hydrates the burn Burnaid Dressings are sterile and exhibit mild biocidal properties – helping to prevent secondary infection.

From a management perspective, Burnaid Dressings provide an effective and simple way of relieving pain and treating burns. The dressing is placed on the burn and stays in-situ for up to two hours. There is no requirement to keep irrigating the burn, nor is there any 'run-off'. Furthermore the need to administer narcotics for pain relief can be greatly reduced. The Dressing doesn't disguise the extent of the burn. When the burn needs to be further examined, the non-adherent dressing simply lifts off and any residual gel rinsed off.

The Burnaid Dressing allows for easy transport to medical attention, as the gel stays 'in-situ' on the skin far better than chilled-water irrigated dressings. Furthermore as the first response treatment in accident and emergency wards or ER's, the Dressing need only be applied once - saving nursing resources and time. The Dressing has many other practical benefits - especially where clean cold water is not readily available.

Burnaid is used throughout industry, in medical centres, by Australian ambulance, and in hospital emergency departments from as far a field as the North Sea Oil rescue services to hospitals in Australia, Singapore and the USA.

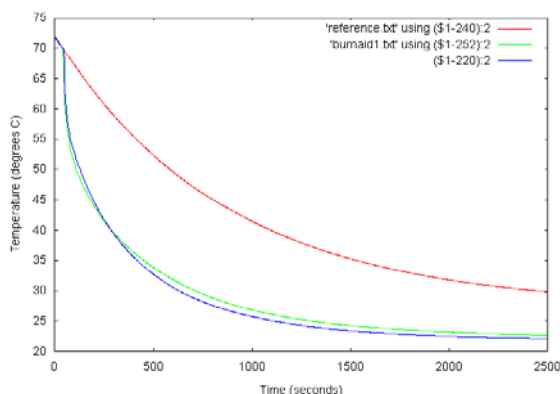
COOLING

Recent clinical studies published in Burns, conducted using Melaleuca alternifolia Hydrogel dressings, compared their performance against tap water as a coolant, for fresh deep partial thickness hot water burns in a porcine model. Clinical and histological assessment at 21 days indicated more rapid healing in both the Melaleuca Hydrogel Dressing and the water-cooled burns compared to the untreated controls. Effective cooling of the burn wound and an increased rate of wound healing was achieved by both repeated tap water compresses and by immediate or delayed application of Melaleuca Hydrogel Dressings. The study concluded that cooling using a Melaleuca Hydrogel Dressings is an effective means to reduce tissue damage and increase wound healing.ⁱ

Heat dissipation testing conducted on Burnaid 10x10cm dressings at Macquarie University Sydney, demonstrated their ability to act as a 'heat sink'. A block of material simulating tissue was heated. At this point a 10x10cm dressing was placed over the heated material. The temperature immediately began to drop, and continued to cool the mass more effectively than the control.ⁱⁱ

Furthermore in-vitro trials conducted of Melaleuca Oil showed that the inflammatory activity of monocytes was regulated by the water-soluble components of Melaleuca Oil. Melaleuca Oil suppresses monocyte production of inflammatory mediators and superoxide and thereby may prevent tissue damage.ⁱⁱⁱ Cooling can also help preserve mast cells and help decrease inflammation. These two actions combined may help reduce tissue damage.

The cooling properties of the Burnaid Gel aid in stopping burn progression and increasing wound healing.



PAIN RELIEF

In-vitro studies conducted at the University of Sydney using Melaleuca Oil on isolated nerve preparations, indicated a classical local anaesthetic action of a reversible nature, but with some apparent difference in mode of action to a common local anaesthetic substance such as procaine.^{iv} This action was observed at dilutions as low as 1/2500.

The Melaleuca Oil in Burnaid combined with a 3mm layer of Burnaid Gel held in-situ by the dressing, provides rapid cooling pain relief to the patient.

INFECTION CONTROL

The antimicrobial activity of one of the ingredients in Burnaid - tea tree oil, is well-documented in scientific literature.

Testing of Burnaid Burn Gel Tubes (4% Melaleuca Oil) in accordance with British Pharmacopoeia Preservative Test indicated Burnaid passed the test.^v

Culture	Control Count	0 hr	6 hr	24 hr	48 hr
S. aureus	1.9x10 ⁷	8.4 x 10 ⁵	<10	<10	<10
Ps. aeruginosa	4.7x10 ⁶	3.6 x 10 ⁵	<10	<10	<10
C. albicans	5.1x10 ⁶	4.0x10 ⁵	<100	<100	<100
A. niger	2.9x10 ⁶	4.7x10 ⁵	3.8x10 ⁵	2.6 x 10 ⁵	<100

Testing of Burnaid Gel (4% Tea Tree Oil) by the Department of Microbiology, Repatriation General Hospital, Concord, Sydney, for activity against a number of organisms expressed as zones of inhibition, indicated activity against all organisms.^{vi}

ORGANISM	ZONE OF INHIBITION (mm)
C. albicans	5
C. tropicalis	11
Staph. aureus 3	40
Staph. aureus 4	47
E. coli 5	30
E. coli 6	24

The results indicate that the active ingredient in Burnaid Gel (Melaleuca Oil – 1.0% w/w Dressings & Sachets, 4% w/w Tubes), exhibits biocidal activity, aiding the prevention of secondary infection. However it must be noted that biocidal activity in 1% gel (dressings) is mild.

SAFETY

Toxicity, Skin Irritation and Sensitisation

In-vivo studies conducted on Burnaid indicate a Draize irritation index of 0 for acute dermal irritation, indicating a non-irritant. Skin sensitization studies indicated slight intradermal irritation reactions, although no sensitization properties are shown. Oral toxicity studies indicate the LD50 to be greater than 10g/Kg - indicating a very low potential toxicity. Burnaid Gel 4% was evaluated as a very mild eye irritant using the Draize procedure.^{vii}

21-day cumulative irritancy testing of a 10% Melaleuca Oil formulation conducted on humans indicated that in general low percentage formulations used topically such as Burnaid would appear to pose little risk of skin irritation when applied under normal conditions.^{viii}

Wound Healing

In-vivo studies examining the effect of tea tree oil on experimental wounds showed that when compared to untreated control wounds, there was no significant difference in healing times indicating the active ingredient in Burnaid - Melaleuca Oil, did not delay wound healing.^{ix}

Sterility

Burnaid Dressings are gamma irradiated at a minimum dosage of 25Kgys. Independent review of the radiation sterilisation practices and laboratory testing procedures used on Burnaid gave a Sterility Assurance Level (SAL) of greater than 10⁻⁶ – ensuring compliance as a sterile medical device under FDA and European Union Sterile Devices Codes.^x

REGULATORY APPROVAL

Burnaid Dressings and sachets are approved for sale under US FDA, European Union CE, Australian TGA, NZ – MOH, and throughout selected countries in Asia and the Middle East.

COMMENTS

A small selection of user feedback;

"...I have had the chance to use Burnaid on a number of occasions for pain management in first and second degree burns. We have nothing but total satisfaction from the ER staff as well as the patients.

The nurses have described Burnaid as "quick and easy to use", providing "total" and "instant relief" of pain from burns. Instead of using cold wet towels that require a lot of nursing time for administration, simply applying Burnaid works so well the nurses are able to concentrate on other patients in the ER...."

Harlan Gibbs M.D.
Medical Director, Emergency Department
Glendale Adventist Medical Center
Glendale, California.

" I am writing to inform you of the amazing response we have had to the use of Burnaid in our Emergency Department. On two separate occasions, I have used Burnaid on small children who have suffered first and second degree burns. In both cases there was immediate relief of the pain.

For one particular child (a ten month old girl) who sustained a second degree burn to the hand, when Burnaid was applied, she stopped crying immediately and "appeared happy and content" to the treating nurse. The ER nurse described Burnaid as "magic" and "its much easier to use than conventional therapy." Instead of injections of narcotics for pain relief, Burnaid has allowed us to treat burns more simply and quickly without the use of sedating drugs or continuous cold, wet towels..."

David Friend, M.D.
1509 Wilson Terrace
Los Angeles
California

"...The operating temperature of the autoclave is 121°C and the steam burn appeared severely over the top of two fingers of the right hand and naturally, the pain was severe.

We applied your product Burnaid immediately, and the effect was amazing to say the least....the response was that the pain reductions was instantaneous. No blistering occurred and only redness resulted..."

Tony Foley
Technical Services Manager
Pilkington Barnes Hind
Sydney

"...The Queensland Ambulance Transport members who have used Burnaid say the patient is certainly made comfortable by its use..."

J.F. Leditschke
Associate Professor in Paediatric Surgery
Royal Children's Hospital
Brisbane

"...I am quite happy for it (Burnaid) to be used in the first aid situation and, in fact, I state this in lectures; a big factor being that it is a non-toxic and water soluble and can easily be removed for examining the burn on admission."

Stuart P. Pegg
Director of Surgery &
Director of Burns Unit
Royal Brisbane Hospital

"...As you may know, it's (Burnaid) a product we endorse for our first aid burn management and treatment of most minor burns..."

Fiona M. Wood
Director of Burns Unit
Royal Perth Hospital

References

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