

Biovite Australia Pty Ltd
Information Sheet for Clinicians

Calmagen[®] NailKalm[®] Dermaceutical Lotion 25mL **(Aust L 148668)**

Active ingredient: *Arthrospira maxima* cell powder (AMYCOT[®]) 8% w/w



PRESENTATION

Lotion for topical application in a 25mL plastic, opaque, screw-cap dropper bottle.

INGREDIENTS

Active ingredient: AMYCOT[®] 8% w/w - (derived from *Arthrospira maxima*)

The active ingredient AMYCOT[®] is a bioactive derived from a species of planktonic Cyanobacteria (blue-green algae), *Arthrospira maxima*, that has been used for centuries as a highly nutritious source of food containing very high levels of essential vitamins, essential amino acids and anti-oxidants.

Other Ingredients:

Purified Water
Paraffin (soft white)
Caprylic/capric triglyceride (Crodamol[™] GTCC)
Cetyl Alcohol
Liquid Paraffin (Mineral Oil)
Phenoxyethanol (preservative)
Cetamacrogol 1000 BP
Fragrance (Tea Rose)

(The lotion also contains trace amounts of benzoic acid and titanium dioxide arising from production of the active ingredient AMYCOT[®]).

DESCRIPTION

The product consists of an aqueous, cream-coloured lotion that readily absorbs into the nails and skin and has a subtle, natural smell. The pH of the lotion is in the same range as normal human skin (pH 5.5 – 6.5).

INDICATIONS

The product is for use in the treatment of dermatophyte/fungal infections of the skin and nails:

- Treatment of ringworm (tinea) infections of the body (tinea corporis), groin (tinea cruris – “jock-itch”), hands (tinea manuum) and feet (tinea pedis – “athlete’s foot” and “moccasin foot”) due to infection by dermatophytes such as *Trichophyton* species (*T. rubrum*, *T. tonsurans*, *T. mentagrophytes*, *T. versicolor*, *T. verrucosum*, *T. violaceum*), *Microsporum canis*, *Epidermophyton floccosum* and *E. folliculosum*.
- Treatment of onychomycosis (tinea unguium - fungal/dermatophyte infection of the fingernails and toenails).
- Treatment of skin infections caused by yeasts such as *Candida albicans* and *Malassezia* species.

CONTRAINDICATIONS

The lotion should not be used in cases of known hypersensitivity to any of the ingredients in the formulation. To test for hypersensitivity, apply a small amount to the inside of the wrist.

ADVERSE EFFECTS

Independent laboratory tests have shown that Calmagen[®] products containing AMYCOT[®] are non-toxic and non-sensitising. There is an extremely low risk of skin irritation or mild local allergic reaction. If this does occur, treatment should be ceased immediately.

EFFICACY

Trials undertaken in Australia, New Zealand, Germany and the United States have demonstrated that Calmagen[®] topical products are rapidly effective in permanently eradicating dermatophyte infections of the skin and/or nails when used as instructed, even in cases of chronic and intractable, deep onychomycosis for which other available treatments had previously been unsuccessful.

Laboratory tests undertaken in New Zealand and Australia have demonstrated that the active ingredient in Calmagen[®] products (AMYCOT[®]) is fungicidal rather than merely fungistatic. Scanning electron microscopy/SEM studies *in vitro* have shown that AMYCOT[®] completely digests the cell walls (of both hyphae and conidia) of target fungal species (resulting in death of the cells). Extensive *in vitro* laboratory testing in Australia and New Zealand of Calmagen[®] products against a comprehensive range of dermatophyte species (and the yeast *Candida albicans*) has demonstrated remarkable efficacy/fungicidal activity against all species tested.

Independent *in vitro* laboratory studies have also shown that Calmagen[®] products are effective in stimulating the growth of skin-derived cells such as keratinocytes (by increasing protein neo-synthesis) and also possess anti-inflammatory properties. These characteristics may explain the relatively rapid repair of skin and nails observed for the products during trials.

DOSAGE / ADMINISTRATION

Apply liberally over the face of the nail, around the margins including the quick and under the nail at least twice a day (night and morning) and rub in well. Use at the first signs of fungal skin or nail conditions of the feet.

Continue to apply as per instructions until skin and/or nails feel and look healthy, skin soft and fresh, nails free of blemishes, healthy and shiny. In the case of badly damaged nails, this may require application for an extended period of time, up to several months depending on the severity of the damage, while the new nail grows out free of damage.

Note: It is recommended that the product be used in conjunction with Calmagen[®] FootKalm[®] Dermaceutical Powder (to eradicate fungal spores from shoes/footwear) and/or Calmagen[®] FootKalm[®] Dermaceutical Cream (for application to affected skin).

STORAGE

Store at room temperature - below 30°C. Do not refrigerate. Do not freeze. Keep away from direct sunlight, UV or other radiation.

SHELF-LIFE

36 months.

For batch number and expiry, see base of carton or product container.

CAUTION

For external use only. All medications should be kept out of reach of children and pets. Avoid contact with the eyes. Contains benzoic acid and phenoxyethanol. If symptoms persist, consult your healthcare practitioner.

PRODUCT ORIGINS

The product was developed and is manufactured in Australia by an Australian owned company.

SPONSOR

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Australian Register of Therapeutic Goods / ARTG Entry: Aust L 148668

This Information Sheet (Version 1.0) prepared: March 2010