

Biovite Australia Pty Ltd
Information Sheet for Clinicians

Calmagen[®] FootKalm[®] Dermaceutical Powder 40g **(Aust L 148908)**

Active ingredient: *Arthrospira maxima* cell powder (AMYCOT[®]) 5% w/w



PRESENTATION

Dusting powder for topical application in a 40g Talc Drum

INGREDIENTS

Active ingredient: AMYCOT[®] 5% 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: Talc
Sodium Bicarbonate

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

DESCRIPTION

The product consists of an off-white, fine, smooth, free-flowing dusting powder with a natural earthy smell.

INDICATIONS

The product is for use in the eradication of fungal spores from shoes/footwear to aid in the treatment of dermatophyte/fungal infections of the skin and nails:

- Treatment of ringworm (tinea) infections of the 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 toenails).

CONTRAINDICATIONS

The powder 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 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 clinical trials.

DOSAGE / ADMINISTRATION

Shake a small amount daily into shoes, socks or stockings (especially the toe area) prior to wearing. Alternatively, the powder may be applied directly to the skin before donning enclosed footwear, socks or stockings. Use at the first signs of fungal skin or nail conditions of the feet. The powder will eradicate fungal spores and help keep feet dry and fresh at times of excessive perspiration during sport or heavy work.

Duration of treatment

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: The product is intended to be used in conjunction with Calmagen[®] SkinKalm[®] Dermaceutical Cream (for the skin) and/or Calmagen[®] SkinKalm[®] Dermaceutical Lotion (for the nails).

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. If symptoms persist, consult your healthcare practitioner.

PRODUCT ORIGINS

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

SPONSOR

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