

16 October, 2015

The Secretary
Medicines Classification Committee
Medsafe
PO Box 5013
Wellington
New Zealand

Dear Sir/Madam,

Re: Classification of ciclopirox for dermal use in medicines containing 1% or less except in medicines for tinea pedis only – Pharmacy Only.

We would like to ask the committee to consider, at its November 2003 meeting, reclassifying the above-mentioned entry for ciclopirox to *'for dermal use in medicines containing 2% or less except in medicines for tinea pedis only – Pharmacy Only'*.

The proposed classification for ciclopirox will harmonise with the current schedule in Australia.

We are enclosing 8 copies of the following information to support this change:

- Overview of active ingredient, product and classification status;
- Correspondence with the National Drugs and Poisons Schedule Committee in Australia.

If you have any enquiries regarding this letter please do not hesitate to contact me.

We look forward to your advice in due course.

Yours faithfully,

Mark Stanton
Regulatory and Technical Affairs Manager

Encl.

Overview

1. International Non-proprietary Name

Ciclopirox; Ciclopirox Olamine

2. Proprietary name(s)

Stieprox Liquid

3. Name of company requesting reclassification

Stiefel Laboratories

4. Dose form and strength

Topical, Solution; 1.5%

5. Pack size

150ml

6. Indications for which change is sought

Dandruff and seborrhoeic dermatitis

7. Present classification of medicine

Ingredient	Conditions (if any)	Classification
Ciclopirox;	for dermal use in medicines for tinea pedis only	General Sale
Ciclopirox;	for dermal use in medicines containing 1% or less except in medicines for tinea pedis only	Pharmacy Only
Ciclopirox;	for dermal use in medicines containing more than 1%	Restricted

Ciclopirox;	except for dermal use	Prescription
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8. Classification sought

Ingredient	Conditions (if any)	Classification
Ciclopirox;	for dermal use in medicines for tinea pedis only	General Sale
Ciclopirox;	for dermal use in medicines containing 2% or less except in medicines for tinea pedis only	Pharmacy Only
Ciclopirox;	for dermal use in medicines containing more than 2%	Restricted
Ciclopirox;	except for dermal use	Prescription

9. Classification status in other countries

Australia

Schedule 2 – CICLOPIROX in preparations for dermal use containing less than 2 per cent of ciclopirox.

Schedule 3 – CICLOPIROX in preparations for dermal use **except** when included in Schedule 2.

Schedule 4 - CICLOPIROX **except** when included in Schedule 2 or 3.

10. Extent of usage in NZ and elsewhere and dates of original consent to distribute.

Pending approval in New Zealand and Australia

11. Labelling or draft labelling for the proposed new presentation

Refer attached artwork

12. Proposed warning statements

Not applicable

13. Other products containing the same active ingredient which would be affected by the proposed change

Batrafen Cream and Solution, containing 1% ciclopirox olamine for skin fungal infections is classified Pharmacy Only Medicine. These products will be unaffected by the proposed change.