

Medsafe consultation submission



Addition of warning statements on labels of topical miconazole-containing medicines	
Name and designation	██████████ ████████████████████
Company/organisation name and address	Mylan New Zealand Limited PO Box 11183, Ellerslie Auckland 1542
Contact phone number and email address	██████████ ████████████████████
I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable)</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
(Reasons for requesting confidentiality must meet Official Information Act 1982 criteria)	
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It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, an organisation that is based in:	
<input checked="" type="checkbox"/> New Zealand	<input type="checkbox"/> Australia <input type="checkbox"/> Other (<i>please specify</i>):
I am, or I represent, a: (<i>tick all that apply</i>)	
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Please return this form to:

Email: medsafeapplications@moh.govt.nz including 'Miconazole warning statements' in the subject line

Or Post: Product Regulation
Medsafe
PO Box 5013
Wellington 6145

Medsafe is seeking comments on:

Whether a warning statement about the interaction between warfarin and miconazole is required for all topical miconazole containing medicines available without prescription.

- If a warning is not required for all products please provide your reasoning

Mylan New Zealand supports Medsafe's proposal for a warning regarding the potential for interaction with warfarin to be included on the labels of all topical miconazole-containing products.

Which of the proposed warning statements about the interaction between warfarin and miconazole is preferred?

- Please provide your reasoning, this will help Medsafe when considering future warning statements

Patients taking warfarin - talk to a healthcare professional before using [this product].

Use of positive statements to give direction is preferred. Moreover, this statement is also congruent with the CMI for miconazole topical cream "Tell your doctor or pharmacist if you are taking anticoagulants, medicines used to prevent blood clots such as warfarin".

Whether the statements required in Australia for intravaginal miconazole products should be included in the Label Statements Database.

- Please provide your reasoning
- Are the statements acceptable or should they be reworded?

Mylan New Zealand considers these to be unnecessary. Miconazole for vaginal use is classified as a restricted medicine and requires consultation with a pharmacist for sale. Pharmacists are adequately trained to identify 'red flags' that may require referral to a doctor and provide information to patients as to when they should seek further medical advice.

It should also be highlighted that the Label Statement Database do not include such statements for topical clotrimazole products, which is similarly indicated for vaginal candidiasis.

What is a suitable target date for implementation:

- Please provide justification

A transition period of 18 months, following the change to the Label Statements Database, is proposed to allow sufficient time for sponsors to adequately manage stock. This is in line with similar labelling consultation outcomes published by Medsafe.

Please include additional pages if necessary.

