

# Medsafe consultation submission



## Addition of warning statements on labels of topical miconazole-containing medicines

<b>Name and designation</b>	
<b>Company/organisation name and address</b>	
<b>Contact phone number and email address</b>	
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 type="checkbox"/> No
(Reasons for requesting confidentiality must meet <a href="#">Official Information Act 1982</a> criteria)	
I would like my name to be removed from all documents prior to publication on the Medsafe website.	<input type="checkbox"/> Yes <input type="checkbox"/> No
I would like for my name not to be included within the list of submissions published on the Medsafe website.	<input type="checkbox"/> Yes <input type="checkbox"/> No

**It would help in the analysis of stakeholder comments if you provide the information requested below.**

<b>I am, or I represent, an organisation that is based in:</b>			
<input type="checkbox"/> New Zealand	<input type="checkbox"/> Australia	<input type="checkbox"/> Other <i>(please specify):</i>	
<b>I am, or I represent, a: <i>(tick all that apply)</i></b>			
<input type="checkbox"/> Importer	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Supplier	<input type="checkbox"/> Sponsor
<input type="checkbox"/> Government	<input type="checkbox"/> Researcher	<input type="checkbox"/> Professional body	<input type="checkbox"/> Industry organisation
<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Member of the public	<input type="checkbox"/> Institution (e.g. university, hospital)	
<input type="checkbox"/> Regulatory affairs consultant	<input type="checkbox"/> Laboratory professional		
<input type="checkbox"/> Health professional – <i>please indicate type of practice:</i>			
<input type="checkbox"/> Other - <i>please specify.</i>			

**Please return this form to:**

**Email:** [medsafeapplications@moh.govt.nz](mailto: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

*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

Please include additional pages if necessary.

*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?

*What is a suitable target date for implementation:*

- Please provide justification