

Medsafe consultation submission



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

Name and designation	
Company/organisation name and address	
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 type="checkbox"/> No
(Reasons for requesting confidentiality must meet Official Information Act 1982 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.

I am, or I represent, an organisation that is based in:			
<input 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>			
<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 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