



Medsafe consultation submission

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

Name and designation	[Redacted]
Company/organisation name and address	The Christchurch Doctors
Contact phone number and email address	[Redacted]
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)	
I would like my name to be removed from all documents prior to publication on the Medsafe website.	<input type="checkbox"/> Yes <input checked="" 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 checked="" 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:

New Zealand Australia Other (please specify):

I am, or I represent, a: (tick all that apply)

- Importer
- Government
- Consumer organisation
- Regulatory affairs consultant
- Health professional – please indicate type of practice: *Sened Practitioner*
- Other - please specify:
- Manufacturer
- Researcher
- Member of the public
- Laboratory professional
- Supplier
- Professional body
- Institution (e.g. university, hospital)
- Sponsor
- Industry organisation

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

I think there should be a warning on all products because the interaction is severe.

I had a patient who took miconazole for one week while on warfarin. INR went from 2.5 → 13.

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

That the interaction is severe and that people on warfarin should not use miconazole or if they do the warfarin must be monitored closely and dose adjusted.

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?

Yes as there once again will be an interaction that could disturb the INR with serious consequences

What is a suitable target date for implementation:

- Please provide justification

As soon as possible.
as serious interaction that could cause people to bleed internally

Please include additional pages if necessary.