Topical corticosteroids: Proposal for the package labelling to state their potency

Overview

Medsafe is seeking your feedback on a proposed advisory statement for topical corticosteroids to include information about the potency (strength) on the container/package label.

In March 2025, the Medicines Adverse Reactions Committee (MARC) reviewed the risk of topical steroid withdrawal reactions. The MARC commented that inappropriate overuse of topical corticosteroids is common and noted the recent action taken by the United Kingdom's medicines regulator, the Medicines and Healthcare products Regulatory Agency, to have topical corticosteroid products labelled with information on their potency. The MARC considered that having potency information on New Zealand labels would be helpful for consumers.

Topical corticosteroids are medicines that are applied to the skin to treat various inflammatory skin conditions, such as eczema, dermatitis and psoriasis. They are available in different potencies (strengths): mild, moderate, potent or very potent. Because topical steroids are absorbed through the skin, they can occasionally cause serious side effects, such as adrenal suppression or Cushing's syndrome. These serious side effects are related to the amount, potency and duration of use of the corticosteroid.

Topical corticosteroid products with one active ingredient are known as 'plain' topical corticosteroids. Some topical corticosteroid products may also include another active ingredient such as an antifungal, antibiotic, antiviral or calcipotriol. These are known as 'combination' products. There more than 50 approved topical corticosteroid products in New Zealand.

Depending on the condition being treated, patients may be prescribed multiple topical corticosteroid products. The products may have different potencies and be used on different areas of the skin for a specified period of time. Some mild potency topical corticosteroids are also available without a prescription.

Having the potency stated on the package labelling has benefits for consumers, including the following.

- Clearer labelling, making it easier for consumers to recognise that the product is a topical corticosteroid. This is important when different products for the skin are being prescribed (eg, moisturisers and soap substitutes).
- For consumers who are prescribed multiple topical corticosteroids with different potencies, labelling may prevent accidental use of stronger corticosteroids on more delicate areas of the body.
- Enhance consumer knowledge and encourage engagement in the management of their skin condition.

The New Zealand Formulary uses the following classification system to describe and group the potency of topical corticosteroids. We propose using the same classification system.

- **Mild**: hydrocortisone
- **Moderate**: clobetasone and triamcinolone acetonide
- **Potent**: betamethasone valerate, betamethasone dipropionate, hydrocortisone butyrate, mometasone furoate, and methylprednisolone aceponate
- **Very potent**: clobetasol propionate and betamethasone dipropionate (in an optimised vehicle).

The Label Statements Database lists the warning and advisory statements that are required on the package labelling for medicines and related products. Currently, there are statements for hydrocortisone, clobetasone and aclometasone, but they are not about the potency of the corticosteroid.

Table 1 outlines the proposed advisory statement for topical corticosteroids.

Table 1: Proposed advisory statement for topical corticosteroids

Substance/Group/Class	Conditions	Statement	Required by
Corticosteroid, topical	For all classifications, including prescription. For dermal use. For plain and combination products containing corticosteroids.	Contains [mildly potent, moderately potent, potent, very potent] corticosteroid	18 months from when the Label Statements Database is updated

Medsafe is seeking your feedback on:

- whether the packaging for topical corticosteroids should have an advisory statement about potency
- the conditions that apply to the label statement
- the required by (implementation) date (see Table 1)
- the terms that should be used to describe the potency and the grouping of the different corticosteroids.

Note that it is generally acceptable that words of a similar meaning can be used for statements in the Label Statements Database, provided the intent is not changed. However, to be consistent across products, the specific terms used to describe the various corticosteroid potencies must be used.

About the consultation

This consultation contains a series of pages, each with a number of questions. The only question you are required to answer is on the 'Publishing submissions and Official Information Act requests' page – where you tell us whether or not you give us permission to publish your submission.

To assist in the analysis of submissions, Medsafe will only accept submissions made through this consultation website. However, the full consultation document is attached below as a PDF, and it can be viewed online, downloaded and/or printed.

To take part in this consultation, click on the 'Online survey' link below.

What happens next

We will carefully consider all submissions. Once we have finished analysing the submissions, we will publish the outcome on the Outcome of Consultations web page on the Medsafe website.

Your details

You are encouraged to fill in this section. The information will help in the analysis of stakeholder comments. Your submission will still be accepted if you do not fill in this section.

1. **What is your name?**

2. **What is your email address?**

3. **Are you providing feedback:**

   - As an individual
   - On behalf of an organisation or group

   Please provide your organisation or group name:

4. **Where are you or your organisation based?**

   - New Zealand
   - Australia
   - Other

   If you selected Other, please specify:

5. **Which of the below options best describes you in the context of this consultation?**

   - Healthcare professional
   - Member of the public
   - Sponsor
   - Manufacturer
   - Supplier
   - Importer
   - Government
   - Researcher
   - Professional body
   - Industry organisation
   - Consumer organisation
   - Institution (eg, university, hospital)
   - Regulatory affairs consultant
   - Laboratory professional
   - Other

   If you selected Healthcare professional, please indicate your type of practice:

   If you selected Other, please specify:

Publishing submissions and Official Information Act requests

We intend to publish the submissions from this consultation, **but we will only publish your submission with your permission**. We will remove personal details such as email addresses and the names of individuals.

Your submission will be subject to requests made under the Official Information Act (even if it hasn't been published). If you would like us to withhold specific information from your submission if we receive an Official Information Act request, please let us know. Reasons might include that it's commercially sensitive or it's personal information. Any decision Medsafe makes to withhold information can be reviewed by the Ombudsman, who may tell us to release it.

6. **May we publish your submission? (Required)**
   - Yes. You may publish this submission
   - No. Do not publish this submission

7. **Is there anything in your submission that you would like us to withhold?**

   Information to withhold:

Proposed advisory statement for topical corticosteroids

The following table shows the proposed advisory statement for topical corticosteroids.

Medicine/Group/Class	Conditions	Statement	Required by
Corticosteroid, topical	For all classifications, including prescription. For dermal use. For plain and combination products containing corticosteroids.	Contains [mildly potent, moderately potent, potent, very potent] corticosteroid	18 months from when the Label Statements Database is updated

8. **Should the package labelling for products containing topical corticosteroids have an advisory statement on its potency?**
   - Yes
   - No

   If no, please tell us why:

9. **Do you agree with the proposed conditions (ie, for all classifications, including prescription; for dermal use; for plain and combination products containing corticosteroids)?**
   - Yes
   - No

   If no, please tell us why:

10. **Do you agree with the proposed implementation timeframe of 18 months following the update of the Label Statements Database on the Medsafe website?**
    - Yes
    - No

    If no, please suggest an alternative timeframe:

Topical corticosteroids – potency terms and grouping

We propose to use the New Zealand Formulary's potency terms and grouping:

- **Mild**: hydrocortisone
- **Moderate**: clobetasone and triamcinolone acetonide
- **Potent**: betamethasone valerate, betamethasone dipropionate, hydrocortisone butyrate, mometasone furoate, and methylprednisolone aceponate
- **Very potent**: clobetasol propionate and betamethasone dipropionate (in an optimised vehicle).

11. Do you agree with the terms 'mildly potent', 'moderately potent', 'potent' and 'very potent' to describe the different corticosteroid potencies?

- Yes
- No

If no, please suggest alternative terms:

12. Do you agree with the assigned groupings for the topical corticosteroids?

- Yes
- No

If no, please suggest alternative groupings:

13. Do you have any other comments?

Please add your comments:

Almost done...

You are about to submit your response. By clicking 'Submit Response' you give us permission to analyse and include your response in our results. After you click Submit Response, you will no longer be able to go back and change any of your answers.

Your email address will not be attached to your response – it will only be used to send your receipt.

If you provide an email address you will be sent a receipt and a link to a PDF copy of your response.

Email address:

Your response has been submitted

Your response ID is XXXX-XXXX-XXXX-X. Please have this ID available if you need to contact us about your response.

A receipt for your response has been emailed to you from the address **no-reply@mail1.citizenspace.com** with the subject "**Response received - Response ID: XXXX-XXXX-XXXX-X**". If it doesn't appear in your inbox within a couple of minutes, please check your "spam" or "junk" folder.

Thank you for your response.