Proposed warning and advisory statement for ocular decongestants used for eye redness and/or minor eye irritation: Do not use in children under 12 years of age

Overview

This Medsafe consultation seeks your feedback on a proposed new warning and advisory statement for the package labelling of ocular decongestants. These are medicines that provide temporary relief of redness and/or minor irritation in the eyes through narrowing of swollen blood vessels.

In June 2021, the Medicines Adverse Reaction Committee (the Committee) noted that the Clear Eyes (naphazoline) 0.01% eye drops package label did not have a lower age limit for use. The Committee expressed concerns that because Clear Eyes is a pharmacy-only medicine, it could be used in children under 12 years inappropriately without further investigation or adequate input from a healthcare professional. The New Zealand Formulary for Children recommends naphazoline should only be used in children 12 years and older. Therefore, the Committee recommended a Label Statements Database consultation to include this age limit on the package labelling.

Following this recommendation, Medsafe is extending this Label Statements Database consultation to include all ocular decongestants when used for eye redness and/or minor eye irritation. Other ocular decongestants available are tetrahydrozoline (tetryzoline) and phenylephrine.

The Label Statements Database lists the warning and advisory statements that are required on medicines and related package labelling. Currently, ocular decongestants are not required to have warning and advisory statements on the package labelling.

Because ocular decongestants are pharmacy-only or general sale medicines, they are not required to have a data sheet or a consumer medicine information leaflet. Instead, care givers and consumers must rely on the information on the package labelling. There is a risk that without adequate warnings on the label, these products may expose the child to unwanted harm. Safety concerns relating to use of ocular decongestants in children include the possibility of systemic effects and lack of safety and efficacy information.

At present, a lower age restriction for use is included on certain ocular decongestant package labelling:

- Naphazoline: some package labels of naphazoline-containing eye drops state that they should not be used in children under 12 years of age, while other products do not have an age limit.
- Tetrahydrozoline: the package labels of tetrahydrozoline-containing drops currently state that they should not be used in children under 6 years of age.
- Phenylephrine: currently there are no phenylephrine eye drops used for eye redness and/or minor eye irritation that are approved in NZ. Phenylephrine is also used for diagnostic procedures; products used for this purpose will not be required to have the proposed warning and advisory statement.

Medsafe is proposing that a lower age recommendation of 12 years old should be reflected across all ocular decongestant product labels.

Table 1 below shows the proposed warning and advisory statement for ocular decongestants.

Table 1: Proposed warning and advisory statement for ocular decongestants

Medicine/Group/Class	Conditions	Statement	Required by
Decongestant, ocular: Examples include: Naphazoline Tetrahydrozoline (tetryzoline) Phenylephrine	For ophthalmic use. When used for eye redness and/or minor eye irritation only. When used in combination with another medicine(s), the age limit for the combination product should reflect the highest age limit overall from each medicine.	Do not use in children under 12 years of age.	12 months from when the Label Statements Database is updated.

Medsafe is seeking your feedback on:

1. whether the package labels for ocular decongestants should contain a warning and advisory statement for an age restriction of use, whether a proposed age restriction of 12 years and under for all ocular decongestants is appropriate, the conditions the label statements will be applied to, and the required by (implementation) date (see Table 1).
2. whether there are any other statements relating to use of ocular decongestants in children that should be included on the package labelling.

Note that if the proposed statement is added to the Label Statements Database, words of a similar meaning to the statement may be used on the package labelling, provided the intent is not changed.

To assist in the analysis of submissions, Medsafe will only accept submissions made through the consultation website: https://consult.health.govt.nz/medsafe/proposed-warning-statement-ocular-decongestants

About this consultation

This consultation is made up of 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.

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/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

6. Publishing submissions

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

If you do not want your submission published, please let us know below.

(Required)
- You may publish this submission
- Do not publish this submission

7. Official Information Act responses

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.

Information to withhold:

Proposed warning and advisory statement for ocular decongestants

The following table shows the proposed warning and advisory statement for ocular decongestants.

Medicine/Group/Class	Conditions	Statement	Required by
Decongestant, ocular: Examples include: Naphazoline Tetrahydrozoline (tetryzoline) Phenylephrine	For ophthalmic use. When used for eye redness and/or minor eye irritation only. When used in combination with another medicine(s), the age limit for the combination product should reflect the highest age limit overall from each medicine.	Do not use in children under 12 years of age.	12 months from when the Label Statements Database is updated.

8. Should the package labelling for ocular decongestants such as naphazoline, tetrahydrozoline or phenylephrine-containing eye drops include a warning statement for an age restriction of use?

- Yes
- No

Please add your comments:

9. Do you agree that the proposed statement: "Do not use in children under 12 years of age" should be applied to all ocular decongestants?

- Yes
- No

If no, please suggest an alternative age restriction for all ocular decongestants or an age restriction for each individual ocular decongestant medicine (naphazoline, tetrahydrozoline, phenylephrine), or suggest an alternative statement:

10. Do you agree with the proposed conditions?

- Yes
- No

If no, please suggest alternative conditions:

11. Are there any other warning and advisory statements relating to use of ocular decongestants in children that should be included on the package labelling?

- Yes
- No

Please add your suggested statement(s):

12. Do you agree with the proposed implementation timeframe of 12 months following the update of the Label Statements Database on the Medsafe website?

- Yes
- No

If no, please suggest an alternative timeframe:

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:

What happens next?

All comments will be considered. Once the analysis of submissions is complete, the Label Statements Database may be updated. We will publish the outcome on the Outcome of Consultations web page on the Medsafe website.