

Canterbury

District Health Board

Te Poari Hauora o Waitaha

ONLINE SUBMISSIONS COVERSHEET

Submission Title:

Proposed changes to the current paracetamol conditions, warning statements and dosing table

Consulting Agency:

Ministry Of Health

HiAP Team Lead:

Silas Thielmann

Submission link:

<https://consult.health.govt.nz/medsafe/paracetamol-warning-and-advisory-statements/>

Questionnaire Questions:

When sold in a liquid oral dose form

1. Do you agree that the two current paracetamol conditions in the Label Statements Database should be replaced by three new conditions for different dosage forms?

Yes No

If no, please suggest alternative conditions or state keep the same

2. Do you agree that the current paracetamol dosing table should be revised?

Yes No

Comments:

The Canterbury DHB agrees that the paracetamol dosing table should be revised. While the weight and age bands are adequate the Canterbury DHB recommends that the table should state a single dose based on the lower age as per the proposed dosing table.

3. Do you agree that the current paracetamol dosing table should be revised to only include one dose per age/weight bracket?

Yes No

Comments:

The Canterbury DHB strongly agrees that the current paracetamol dosing table should be revised to only include one dose per age/weight bracket as this is much less confusing for consumers.

4. The proposed paracetamol dosing table provides one dose per age/weight bracket that is calculated from the maximum recommended dose for the low-end weight of the age/weight bracket (ie, 15 mg/kg). This means that a minimum dose of 10 mg/kg is achieved for the high-end weight of the age/weight bracket – Do you think that this is appropriate?

Yes No

If no, do you have suggestions for alternative dosing recommendations?

The Canterbury DHB agrees with the proposed paracetamol dosing table that provides one dose per age/weight bracket that is calculated from the maximum recommended dose for the low-end weight of the age/weight bracket. The Canterbury DHB deems it as much safer to have slightly less paracetamol mg/kg than too much.

5. The proposed paracetamol dosing table provides an additional age/weight bracket for consumers >12 years with a weight between 42 kg and 60 kg in line with Martindale. This is in order to better capture those consumers whose weight is not high enough to take a full 1 g adult dose – Do you think that this is appropriate?

Yes No

If no, do you have suggestions for alternative dosing recommendations?

The Canterbury DHB is in support of the proposed paracetamol dosing table provides an additional age/weight bracket for consumers >12 years with a weight between 42 kg and 60 kg as many teenagers do not get to higher weights for several years and 1000mg is reserved for 65kg plus.

6. In the proposed paracetamol dosing table, should the volume be absolute or rounded to the nearest 0.5 mL (shaded column)?

Absolute Rounded to nearest 0.5 mL

If you don't agree with either option, do you have suggestions for alternative dosing recommendations?

The Canterbury DHB strongly supports with the proposed rounding down to the nearest 0.5ml as this way only one column needed. Consequently a rounded dose is far more practical and safer for parents to measure.

7. If the dose is greater than the total of the syringe provided in the packaging, should this be given as two administrations (for example, if the dose is 7.5 mL should the label statement be one 5 mL dose plus one 2.5 mL dose)?

Yes No

If no, do you have suggestions for alternative dosing recommendations?

The Canterbury DHB agrees with the proposed split label statement if the syringe is too small. However, the Canterbury DHB believes that a better alternative is that parents are offered a larger syringe at the point of sale. Additionally the Canterbury DHB suggests that it would be good for all paracetamol to be sold in pharmacies to illustrate the importance of safety.

8. Medsafe proposes removing the possibility for sponsors to use wider age/weight brackets on their packaging/labelling, so that only the age/weight brackets shown in the proposed paracetamol dosing table are used. This is in order to ensure that consumers receive an accurate dose – Do you agree with this?

Yes No

If no, why not?

9. Should packaging for liquid oral paracetamol include the measuring device to enable accurate dosing?

Yes No

If no, why not?

The Canterbury DHB agrees that a measuring device should be included to enable accurate dosing. However, the Canterbury DHB highlights that oral syringes are currently not funded and if they are not supplied alternative devices such as spoons could be used inaccurately.

For this reason the Canterbury DHB reiterates the recommendation highlighted in Question 4 that patients should be offered a syringe at the point of sale and that the syringe should be funded and large enough to hold the required dose.

10. Do you agree with the proposed changes to the paracetamol warning statements for 'when sold in liquid oral dose form'?

Yes No

If no, why not?

11. Are there any additional warning statements you think would be appropriate to include in the proposed condition for paracetamol 'when sold in a liquid oral dose form'?

Yes No

If yes, please suggest additional statements

The Canterbury DHB recommends to consider including advice around liver toxicity and caution with/avoiding alcohol (for the 250 mg/5 mL strength which is also used in adults) in the warning statements.

12. Do you have any other comments about the proposed condition for paracetamol 'when sold in a liquid oral dose form'?

Yes No

Comments:

The Canterbury DHB would like to note the potential concern around dosage information being provided for young children (<6 years) for 250mg/5ml dose –risk of confusion (and increased risk of accidental overdose) particularly when 250/5 strength comes in strawberry flavour OTC but on prescription, strawberry flavour is 120/5.

The Canterbury DHB would also suggest to use the word container instead of carton as parents will throw away cardboard packaging and only keep the bottle in the majority of cases

All other dosage forms, excluding modified release

The attached document contains the current and proposed warning statements for all other dosage forms of paracetamol, excluding modified release.

1. Do you agree with the proposed changes to the paracetamol warning statements for 'all other dosage forms, excluding modified release'?

Yes No

If no, why not?

2. Are there any additional warning statements you think would be appropriate to include in the proposed condition for 'all other dosage forms, excluding modified release'?

Yes No

If yes, please suggest additional statements.

The Canterbury DHB recommends clarification around the term "a few days" for adult use as the term 'few' is very ambiguous.

The Canterbury DHB recommends an upper age limit for adolescents for maximum usage of 48 hours. Depending on your background this could be interpreted several different ways.

The Canterbury DHB recommends proposed changes consider including advice around liver toxicity and caution with/avoiding alcohol.

The Canterbury DHB recommends changing dosing to state maximum of 4g in 24 hours rather than 4 doses as some patients may take one tablet rather than two but could still take a maximum of 4g in 24 hours.

3. Do you have any other comments about the proposed condition 'all other dosage forms, excluding modified release'?

Yes No

Comments

Modified release paracetamol

The attached document contains the current and proposed warning statements for modified release paracetamol.

1. Do you agree with the proposed changes to the paracetamol warning statements for 'modified release'?

Yes No

If no, why not?

2. Are there any additional warning statements you think would be appropriate to include in the proposed condition 'modified release'?

Yes No

If yes, please suggest additional statements

The Canterbury DHB recommends clarification around the term ‘a few days’ for adult use – how many days constitutes a ‘few’ is very ambiguous as noted in the questions related to all other dosage forms excluding modified release.

The Canterbury DHB recommends highlighting an upper age limit for adolescents for maximum usage of 48 hours - depending on your background this could be interpreted several different ways as noted in the questions related to all other dosage forms excluding modified release.

The Canterbury DHB recommends considering including advice around liver toxicity and caution with/avoiding alcohol as noted in the questions related to all other dosage forms excluding modified release.

The Canterbury DHB recommends changing dosing to state maximum of 4 g in 24 hours rather than 4 doses as some patients may take one tablet rather than two but could still take a maximum of 4g in 24 hours, as noted in the questions related to all other dosage forms excluding modified release.

3. Do you have any other comments about the proposed condition ‘modified release’?

Yes No

Comments

Implementation date

1. Do you agree with the proposed implementation timeframe of 18 months following the publication of the consultation outcome on the Medsafe website?

Yes No

If no, please suggest an alternative timeframe

The Canterbury DHB recommends that if accepted this warning information should be made available for pharmacies to provide to consumers with the current labelled products while manufacturers update their packaging.

Other comments

1. Do you have any other comments?

Yes No

Contact details

Silas Thielmann

For and on behalf of

Community and Public Health

C/- Canterbury District Health Board

PO Box 1475

Christchurch 8140

P +64 3 364 1777

F +64 3 379 6488

Silas.thielmann@cdhb.health.nz