

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

Overview

Medsafe is seeking comments on proposed changes to current warning and advisory statements for paracetamol.

At the December 2018 Medicines Adverse Reactions Committee (MARC) meeting, the Committee discussed a serious case report of acute liver failure in a young patient due to a suspected overdose of paracetamol. The Committee noted that they had discussed similar case reports in the past, indicating an ongoing issue ([December 2018 Medicines Adverse Reactions Committee Meeting Minutes](#)).

The [Label Statements Database](#) lists the warning and advisory statements that are required on [medicine](#) and [related product](#) labels under the Medicines Regulations 1984. Currently, the Label Statements Database has different required statements for paracetamol legacy labelling not changed since 2013. The current statements are grouped under the following conditions:

- new product applications from 1 December 2013 AND new labels for existing products from 1 December 2013
- existing products for which no changes to labels are made.

Medsafe proposes removing the current paracetamol conditions and grouping the required warning statements in dose form groups, under the following conditions:

- when sold in a liquid oral dose form
- all other dosage forms, excluding modified release
- modified release

We are seeking your views on the proposed paracetamol conditions, warning statements and dosing table. To help you with your submission, we have described the rationale for the proposed changes in the consultation document below. We will implement these new labelling requirements after this consultation through the Label Statements Database.

Medsafe is seeking your comments on:

- whether the required paracetamol warning statements should be specific to the proposed dose form groups (conditions)
- whether the proposed paracetamol dosing table is appropriate and whether a measuring device should be provided
- whether the proposed warning statements include all relevant paracetamol warning statements for each dose form group (conditions)
- whether any of the proposed paracetamol warning statements are unnecessary for the relevant dose form group, and if yes, why.

Medsafe proposes that the new label statements should be implemented within 18 months from the publication of the consultation outcome on the Medsafe website.

To assist in the analysis of submissions, Medsafe will only accept submissions made through this consultation website.

Give Us Your Views

Go to survey >

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

<Please use the online survey tool to submit your response>

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?

If you enter your email address then you will automatically receive an acknowledgement email when you submit your response.

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

Publishing your submission

We intend to publish the submissions from this consultation, but only if we are given permission to do so.

Official Information Act requests

Your submission may be subject to requests made under the [Official Information Act](#) 1982 (even if it hasn't been published). The Act says we have to make a submission available unless we have a good reason for withholding it.

<Please use the online survey tool to submit your response>

1. Do you give us permission to publish your submission?

(Required)

- Yes. You may publish this submission, including my personal details (name, organisation)
- Yes. You may publish this submission but only after removing my personal details (name, organisation)
- No. Do not publish this submission

2. 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.

Please specify what information in your submission you believe should be withheld, and why.

When sold in a liquid oral dose form

The following tables show the current and proposed warning statements and the current and proposing dosing table when paracetamol is sold in a liquid oral dose form. Please use these tables to answer the questions below.

Current warning statements

Medicine/Group/Class	Conditions	Statement	Required by
Paracetamol	<ul style="list-style-type: none"> New product applications from 1 December 2013 New labels for existing products from 1 December 2013 	<ul style="list-style-type: none"> Dosage (every four to six hours with no more than four doses in 24 hours). [Either] Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised by a doctor. [and/or] Children and adolescents: Keep to the recommended dose. Do not take this medicine for longer than 48 hours at a time unless advised by a doctor. [and] If you know that your child's weight is less than the weight corresponding to the age in the table, choose the dose for their weight. [and] If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well because of the risk of delayed, serious liver damage. [and] Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist. 	1/12/2013
	<ul style="list-style-type: none"> Existing products for which no changes to labels are made 	<ul style="list-style-type: none"> Dosage (these dose instructions are based on the policy that liquid dose forms should be consistent in strength, i.e. 120 mg/5 mL or 250 mg/5 mL - reserving the 250 mg/5 mL concentration for adults): 3 to 12 months old: 60 to 120 mg up to 4 times a day 1 to 5 years old: 120 to 250 mg up to 4 times a day 6 to 12 years old: 250 to 500 mg up to 4 times a day 12 years old and over: 500 to 1000 mg up to 4 times a day Prolonged or excessive use can be harmful. Do not use for longer than 48 hours except on doctor's advice. 	

Proposed warning statements

Medicine/Group/Class	Conditions	Statement	Required by
Paracetamol	When sold in a liquid oral dose form	<ul style="list-style-type: none"> • Dose: every four to six hours when required, up to four doses in 24 hours. • Keep to the recommended dose. • Use the dose for your child's weight. Only use the dose for age if you do not know your child's weight. • If you think you may have given/taken too much paracetamol ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well. It can take time before paracetamol has a damaging effect on your liver. • Do not give or take with other products containing paracetamol. • Keep out of reach and sight of children. • Children and adolescents: Do not give/take this medicine for longer than 48 hours at a time unless advised by a doctor. • [and if intended for use in adults] Adults: Do not take this medicine for longer than a few days at a time unless advised by a doctor. • Keep this carton for future reference to the dosing table. 	XX/XX/XXXX

Justification

Justification for the proposed changes has been provided underneath each proposed statement below.

- Dose: every four to six hours when required, up to four doses in 24 hours.
 - Medsafe proposes inclusion of 'when required' in the dosage instructions as it implies that paracetamol liquid should only be given/taken when it is needed.
- Keep to the recommended dose.
 - Medsafe proposes having this as a standalone statement as it applies to all consumers using this medicine.
- Use the dose for your child's weight. Only use the dose for age if you do not know your child's weight.
 - Medsafe considers improving the current statement by taking into account children that may be lighter or heavier than the weight range given for their age.

- If you think you may have given/taken too much paracetamol ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well. It can take time before paracetamol has a damaging effect on your liver.
 - Medsafe proposes rewording this statement to use more consumer-friendly wording (ie, 'too much paracetamol', as opposed to 'an overdose').
- Do not give or take with other products containing paracetamol.
 - Medsafe proposes removing the clause 'unless advised to do so by a doctor or pharmacist' from this warning statement in order to discourage the use of multiple paracetamol-containing products at one time.
- Keep out of reach and sight of children.
 - Medsafe proposes adding this additional warning to encourage safe storage of paracetamol.
- Children and adolescents: Do not give/take this medicine for longer than 48 hours at a time unless advised by a doctor.
 - Medsafe proposes rewording as children are going to be more likely to be dosed by the parent/caregiver.
- [and if intended for use in adults] Adults: Do not take this medicine for longer than a few days at a time unless advised by a doctor.
 - Medsafe proposes inclusion of this statement as some paracetamol liquid products are marketed for use in adults.
- Keep this carton for future reference to the dosing table.
 - Medsafe proposes adding this additional warning so the dosing table on the packaging can be referred to at a later date when the child may require a different dose.

Current dosing table

These dose instructions are based on the policy that liquid dose forms should be consistent in strength, i.e. 120 mg/5 mL or 250 mg/ 5mL – reserving the 250 mg/5 mL concentration for adults. The recommended dose should be able to be measured using commonly available metric measuring devices.

Age	Average body weight (kg)	Single dose (mg)
1–3 months	4–6	60–90
3–6 months	6–8	90–120
6–12 months	8–10	120–150
1–2 years	10–12	150–180
2–3 years	12–14	180–210
3–4 years	14–16	210–240
4–5 years	16–18	240–270
5–6 years	18–20	270–300
6–7 years	20–22	300–330
7–8 years	22–25	330–375
8–9 years	25–28	375–420
9–10 years	28–32	420–480
10–11 years	32–36	480–540
11–12 years	36–41	540–615
>12 years	500 to 1000 mg. Dosage should not exceed 4 g in 24 hours.	

Wider age ranges (e.g. 1–3 years) may be used on product labelling where appropriate. A medicine label may include only a subset of the age groups – for example, dosing for ages 6–12 years only. Doses must still be consistent with the above table.

Proposed dosing table

The following table is the proposed dosing table for paracetamol when sold in a liquid oral dose form.

Age	Average body weight (kg)	Single dose (mg)	Strength: 120 mg/5 mL		Strength: 250 mg/5 mL	
			Volume – absolute (mL)	Volume – rounded (nearest 0.5 mL)	Volume – absolute (mL)	Volume – rounded (nearest 0.5 mL)
1–3 months	4–6	60	2.5	2.5	1.2	1.2*
3–6 months	7–8	105	4.4	4.5	2.1	2.0
6–12 months	9–10	135	5.6	5.5	2.7	2.5
1–2 years	11–12	165	6.9	7.0	3.3	3.5
2–3 years	13–14	195	8.1	8.0	3.9	4.0
3–4 years	15–16	225	9.4	9.5	4.5	4.5
4–5 years	17–18	255	10.6	10.5	5.1	5.0
5–6 years	19–20	285	11.9	12.0	5.7	5.5
6–7 years	21–22	315	13.1	13.0	6.3	6.5
7–8 years	23–25	345	14.4	14.5	6.9	7.0
8–9 years	26–28	390	16.3	16.5	7.8	8.0
9–10 years	29–32	435	18.1	18.0	8.7	8.5
10–11 years	33–36	495	20.6	20.5	9.9	10.0
11–12 years	37–41	555	23.1	23.0	11.1	11.0
>12 years	42–60	630	26.2	26.0	12.6	12.5
>12 years	Over 60 kg: 500 to 1000 mg. Dosage should not exceed 4 g in 24 hours.		20.8–41.7	21–41.5	10–20	10–20

* This dose has not been rounded as rounding down would lead to an underdose and rounding up to an overdose.

These dose instructions are based on the policy that liquid dose forms should be consistent in strength, i.e. 120 mg/5 mL or 250 mg/5 mL. The recommended dose should be able to be measured using commonly available metric measuring devices, ideally provided with the medicine.

A medicine label may include only a subset of the age groups – for example, dosing for ages 6–12 years only. Doses must still be consistent with the above table. The label should only include mL dosing information for the relevant strength.

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.

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.

Questions

<Please use the online survey tool to submit your response>

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/Comment box – 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/Comment box

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

Yes/No/Comment box

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/Comment box – if no, do you have suggestions for alternative dosing recommendations?

- 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/Comment box – if no, why not?
- 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/Comment box – if you don't agree with either option, do you have suggestions for alternative dosing recommendations?
- 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/Comment box – if no, do you have suggestions for alternative dosing recommendations?
- 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/Comment box – if no, why not?
- 9. Should packaging for liquid oral paracetamol include the measuring device to enable accurate dosing?**
Yes/No/Comment box – if no, why not?
- 10. Do you agree with the proposed changes to the paracetamol warning statements for 'when sold in liquid oral dose form'?**
Yes/No/Comment box – 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/Comment box – if yes, please suggest additional statements.
- 12. Do you have any other comments about the proposed condition for paracetamol 'when sold in a liquid oral dose form'?**
Yes/No/Comment box

All other dosage forms, excluding modified release

The following tables show the current and proposed warning statements for all other paracetamol dosage forms, excluding modified release. Please use these tables to answer the questions below.

Current warning statements

Medicine/Group/Class	Conditions	Statement	Required by
Paracetamol	<ul style="list-style-type: none"> New product applications from 1 December 2013 New labels for existing products from 1 December 2013 	<ul style="list-style-type: none"> Dosage (every four to six hours with no more than four doses in 24 hours). [Either] Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised by a doctor. [and/or] Children and adolescents: Keep to the recommended dose. Do not take this medicine for longer than 48 hours at a time unless advised by a doctor. [and] If you know that your child's weight is less than the weight corresponding to the age in the table, choose the dose for their weight. [and] If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well because of the risk of delayed, serious liver damage. [and] Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist. 	1/12/2013
	<ul style="list-style-type: none"> Existing products for which no changes to labels are made 	<ul style="list-style-type: none"> Dosage (these dose instructions are based on the policy that liquid dose forms should be consistent in strength, i.e. 120 mg/5 mL or 250 mg/5 mL - reserving the 250 mg/5 mL concentration for adults): 3 to 12 months old: 60 to 120 mg up to 4 times a day 1 to 5 years old: 120 to 250 mg up to 4 times a day 6 to 12 years old: 250 to 500 mg up to 4 times a day 12 years old and over: 500 to 1000 mg up to 4 times a day Prolonged or excessive use can be harmful. Do not use for longer than 48 hours except on doctor's advice. 	

Proposed warning statements

Medicine/Group/Class	Conditions	Statement	Required by
Paracetamol	All other dosage forms, excluding modified release.	<ul style="list-style-type: none"> • Dose: every four to six hours when required. Maximum of four doses in 24 hours. • Keep to the recommended dose. • If you think you may have taken too much paracetamol ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well. It can take time before paracetamol has a damaging effect on your liver. • Do not take with other products containing paracetamol. • Keep out of reach and sight of children. • Adults: Do not take this medicine for longer than a few days at a time unless advised by a doctor. • Children and adolescents 11 years and above: Do not take this medicine for longer than 48 hours at a time unless advised by a doctor. 	XX/XX/XXXX

Justification

Justification for the proposed changes has been provided underneath each proposed statement below.

- Dose: every four to six hours when required. Maximum of four doses in 24 hours.
 - Medsafe proposes inclusion of 'when required' in the dosage instructions as it implies that the medicine should only be given/taken when it is needed.
- Keep to the recommended dose.
 - Medsafe proposes having this as a standalone statement as it applies to all consumers using this medicine.
- If you think you may have taken too much paracetamol ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well. It can take time before paracetamol has a damaging effect on your liver.
 - Medsafe proposes rewording this statement to use more consumer-friendly wording (ie, 'too much paracetamol', as opposed to 'an overdose').

- Do not take with other products containing paracetamol.
 - Medsafe proposes removing the 'unless advised to do so by a doctor or pharmacist' in order to discourage the use of multiple paracetamol-containing products at one time leading to inadvertent overdose.
- Keep out of reach and sight of children.
 - Medsafe proposes adding this additional warning to encourage safe storage of paracetamol.
- Adults: Do not take this medicine for longer than a few days at a time unless advised by a doctor.
 - No change proposed.
- Children and adolescents 11 years and above: Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.
 - Medsafe proposes adding this additional information for the use of the 500 mg tablet in children 11 years and above.

Questions

<Please use the online survey tool to submit your response>

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

Yes/No/Comment box – 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/Comment box – if yes, please suggest additional statements.

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

Yes/No/Comment box

Modified release paracetamol

The following tables show the current and proposed warning statements for modified release paracetamol. Please use these tables to answer the questions below.

Current warning statements

Medicine/Group/Class	Conditions	Statement	Required by
Paracetamol	<ul style="list-style-type: none"> New product applications from 1 December 2013 New labels for existing products from 1 December 2013 	<ul style="list-style-type: none"> Dosage (every four to six hours with no more than four doses in 24 hours). [Either] Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised by a doctor. [and/or] Children and adolescents: Keep to the recommended dose. Do not take this medicine for longer than 48 hours at a time unless advised by a doctor. [and] If you know that your child's weight is less than the weight corresponding to the age in the table, choose the dose for their weight. [and] If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well because of the risk of delayed, serious liver damage. [and] Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist. 	1/12/2013
	<ul style="list-style-type: none"> Existing products for which no changes to labels are made 	<ul style="list-style-type: none"> Dosage (these dose instructions are based on the policy that liquid dose forms should be consistent in strength, i.e. 120 mg/5 mL or 250 mg/ 5mL - reserving the 250 mg/5 mL concentration for adults): 3 to 12 months old: 60 to 120 mg up to 4 times a day 1 to 5 years old: 120 to 250 mg up to 4 times a day 6 to 12 years old: 250 to 500 mg up to 4 times a day 12 years old and over: 500 to 1000 mg up to 4 times a day Prolonged or excessive use can be harmful. Do not use for longer than 48 hours except on doctor's advice. 	

Proposed warning statements

Medicine/Group/Class	Conditions	Statement	Required by
Paracetamol	Modified release	<ul style="list-style-type: none"> • Dose: every six to eight hours when required. Maximum of six tablets in 24 hours. • Do not exceed the maximum dose. • If you think you may have taken too much paracetamol ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well. It can take time before paracetamol has a damaging effect on your liver. • Do not take with other products containing paracetamol. • Keep out of reach and sight of children. • Adults: Do not take this medicine for longer than a few days at a time unless advised by a doctor. • Adolescents: Do not take this medicine for longer than 48 hours at a time unless advised by a doctor. • Children: Do not use in children under 12 years. 	XX/XX/XXXX

Justification

Justification for the proposed changes has been provided underneath each proposed statement below.

- Dose: every six to eight hours when required. Maximum of six tablets in 24 hours.
 - Medsafe proposes having this as a standalone statement as it applies to all consumers using this medicine.
- Do not exceed the maximum dose.
 - Medsafe proposes adding this additional warning to encourage safe use of modified release dose forms.
- If you think you may have taken too much paracetamol ring the Poisons Information Centre (Australia 131 126; New Zealand 0800 764 766) or go to a hospital straight away even if you feel well. It can take time before paracetamol has a damaging effect on your liver.
 - Medsafe proposes rewording this statement to use more consumer-friendly wording (ie, 'too much paracetamol', as opposed to 'an overdose').
- Do not take with other products containing paracetamol.
 - Medsafe proposes removing the 'unless advised to do so by a doctor or pharmacist' in order to discourage the use of multiple paracetamol-containing products at one time.

- Keep out of reach and sight of children.
 - Medsafe proposes adding this additional warning to encourage safe storage of paracetamol.
- Adults: Do not take this medicine for longer than a few days at a time unless advised by a doctor.
 - No change proposed.
- Adolescents: Do not take this medicine for longer than 48 hours at a time unless advised by a doctor.
 - Medsafe proposes splitting the current warning statement 'Children and adolescents' into 'adolescents' and 'children' as not all dosage forms of paracetamol that are suitable for adolescents are suitable/intended for children.
- Children: Do not use in children under 12 years.
 - Medsafe proposes adding this additional warning as modified release dose form is not recommended for children under 12 years.

Questions

<Please use the online survey tool to submit your response>

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

Yes/No/Comment box – 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/Comment box – if yes, please suggest additional statements.

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

Yes/No/Comment box

Implementation date

<Please use the online survey tool to submit your response>

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/Comment box – if no, please suggest an alternative timeframe

Other comments

<Please use the online survey tool to submit your response>

1. Do you have any other comments?

Yes/No/Comment box.

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.

To subscribe to an automatic email notification of Medsafe website updates, please register [here](#).