

Guideline for prescribing weight-adjusted ORAL paracetamol in adults

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Background

Paracetamol is a non-opioid analgesic recommended for the first-line management of mild to moderate pain and pyrexia, safe in all patients except for those with risk factors. It can cause liver damage in patients who have certain identifiable risks factors; therefore, therapeutic dosing may need to be reduced. Initial pain assessment, regular clinical review and reassessment of effectiveness, adverse effects and any potential risk factors are crucial to optimal pain management. Consider each person as an individual and take a holistic, collaborative approach. In all patients, the lowest dose which manages the patient's pain should be used.

Risk Factors for hepatotoxicity and inadvertent paracetamol overdose

- **Body weight less than 50 kg**

- Whilst low body weight alone is not considered a marker for an increased risk of oral paracetamol toxicity, an adult patient weighing less than 50kg is more likely to have other conditions which may pre-dispose them to liver damage from paracetamol. Dry body weight is the weight at which the patient is considered "normally hydrated" without extra fluid. Consider dry weight for patients who retain fluids as seen in patients with renal impairment who undergo dialysis, in heart failure and in liver failure.
- It should be remembered that 50kg is a relatively arbitrary border, and patients weighing more than this may also have conditions which mean consideration of a dose reduction would also be appropriate.

- **Chronic alcohol consumption**

- Regular consumption of more than the maximum recommended amount of alcohol (14 units a week).

- **Chronic malnutrition and / or Chronic dehydration**

- Consider reviewing patients acutely not eating and/or drinking for a few days.
- Consider reviewing patients with risk of renal impairment: in cases of dehydration and acute kidney injury.

- **Malnourished patients, with nutritional deficiency and/or chronic debilitating illness**

- Likely to deplete glutathione concentrations and exerting a direct hepatotoxic effect are conditions such as eating disorders (anorexia or bulimia), cystic fibrosis, AIDS, cachexia, Hepatitis C.

- **Cardiac, pulmonary, or renal insufficiency**

- **Severe liver disease**

- Pharmacokinetics of paracetamol is altered in severe liver disease and the hazards of overdose are greater in people with non-cirrhotic alcoholic liver disease.

- **Increasing age and / or frailty**

- A reduction of the clearance of paracetamol has been associated with increased age and frailty.
- Old age is not a risk factor in itself, and older people who are in good health and weigh over 50kg are unlikely to need a dose reduction.
- However, age may be accompanied by frailty and other risk factors. Elderly people might have comorbidities and polypharmacy, which can further increase risk of inadvertent paracetamol toxicity and overdose.

- **Long-term paracetamol use** (especially in those who are malnourished).

- **Hepatic enzyme induction or evidence of on-going liver injury e.g., long term treatment with liver enzyme-inducing drugs** (e.g., carbamazepine, isoniazid, phenobarbital, phenytoin, primidone, rifampicin, rifabutin, efavirenz, nevirapine, St John's Wort).

Key Prescribing Points for ORAL paracetamol dose adjustments in adults

Clinical judgement should be used to dose / adjust the dose of oral paracetamol in patients with Risk Factors

1. **Document up to date weight.**
 - Weight from within the past 4 weeks or depending on risk factors, weigh more regularly. Dry weight should be used.
2. **Assess the patient for risk factors.**
3. **If risk factors are present consider a DOSE REDUCTION.**
 - A lower starting dose and/or reduced frequency of dosing may be appropriate (see page 3).
 - Advise the patient that they have been prescribed a lower dose and explain the reason why.
 - Patients who require a dosage adjustment must be advised that this may be lower than the maximum paracetamol dose recommended in patient information leaflet.
 - If recommending a dose reduction, monitor pain control and offer alternate management strategies if needed.
4. **Before administering, check when oral paracetamol was last administered and cumulative paracetamol dose over previous 24 hours.**
 - Follow the correct dosage interval.
 - Do not exceed four doses of paracetamol in 24 hours.
5. **Irrespective of weight where the patient's creatinine clearance (or absolute glomerular filtration rate) is less 30mL/minute, the interval between dosing must be a minimum of 6 hours.**

Use creatinine clearance to adjust drug doses:

 - In patients with a BMI < 18 kg/m² or > 40 kg/m².
 - In patients at both extremes of muscle mass.
6. **Advise caution when using over the counter or regular paracetamol-containing products (e.g., Co-codamol, Co-dydramol).**
 - The recommended maximum total daily dosage must not be exceeded.
 - If a reduction in paracetamol dose is indicated individual components should be prescribed.
7. **Use of Prokinetics (e.g., metoclopramide or domperidone) will enhance gastric emptying and may increase the rate of paracetamol absorption.**
 - Therefore, a reduction in the amount or frequency of paracetamol dosing may be appropriate.
8. **Anticoagulants**
 - The effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol, with increased risk of bleeding.
 - Monitor international normalized ratio (INR).
9. **Colestyramine**
 - May reduce absorption if given within 1 hour of paracetamol.
 - Separate administration by 1 to 2 hours.
10. **Where applicable, e.g., in a person with swallowing difficulty, consider using paracetamol suspension in place of effervescent preparations due to the high sodium content (6 g salt in a 4 g per 24 hours dose).**
 - Avoid effervescent preparations of paracetamol where possible, particularly in people with hypertension, heart failure, and renal failure.
11. **Monitor liver function tests.**
12. **In a care home or domiciliary setting, ensure that the outcome is recorded and monitored.**
 - To assess paracetamol outcome, use a validated pain assessment tool e.g., Abbey pain scale tool (see reference 24) for those who cannot communicate their pain needs.
 - It is crucial that assessment and treatment of pain is undertaken routinely for all patients.

Dose of ORAL paracetamol in ADULT patients WITHOUT Risk Factors

500 mg – 1 g every 4 - 6 hours as required.

Maximum 4 g in 24 hours

Recommended dose adjustments of ORAL paracetamol in ADULT patients WITH Risk Factors

<u>Weight:</u>	Adults weighing ≤ 33 kg	Adults weighing 34kg-41 kg	Adults weighing 42 kg - 49 kg	* Adults weighing ≥50 kg
<u>Oral dose:</u>	Dose reduction is required: 15mg / kg per dose	500 mg	500 mg - 1 g	500 mg - 1 g
<u>Frequency of Administration:</u> (See Renal Impairment below)	every 4 - 6 hours as required.			
	Always leave at least 4 hours between doses.			
	Do not exceed four doses of paracetamol in 24 hours.			
<u>Maximum daily Dose:</u>	Maximum: 60 mg / kg in 24 hours	Maximum 2 g in 24 hours	Maximum 3 g in 24 hours	Maximum 4 g in 24 hours
	* Use clinical judgement to adjust the dose to a maximum 3 g in 24 hours or use 15mg/kg every 4–6 hours (maximum of 60 mg/kg in 24 hours) as a guide for people with risk factors for hepatotoxicity weighing over 50kg. Dry weight should be used where applicable. Final dose to be determined on an individual basis, considering the underlying disease state and any risk factors of the patient. Review and assess risk factors regularly.			
<u>Renal Impairment:</u> if creatinine clearance is less than 30 mL/minute. <ul style="list-style-type: none">- Increase the minimum dosing interval to 6 hours.- Dose according to weight and risk factors.				

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