Paracetamol – prescribing weight-adjusted paracetamol in adults in the community

– see www.lancashireandsouthcumbriaformulary.nhs.uk for further details

This guidance applies to **oral** paracetamol only - guidance on the dosing of intravenous paracetamol for patients under 50kg is available in the BNF **and** product literature should be followed.

Please note: patients of hospital trusts should be managed in accordance with trust guidance, where this exists

Background

Paracetamol is primarily metabolised in the liver via glucuronidation and sulfation, with a small portion converted by CYP450 enzymes into N-acetyl-p-benzoquinone imine (NAPQI), a hepatotoxic metabolite. At normal doses, NAPQI is detoxified by conjugation with glutathione and excreted in urine. In overdose, the main pathways become saturated, leading to increased NAPQI formation; when glutathione is depleted, NAPQI accumulates and causes liver damage.

Pharmacokinetics may change in severe liver disease. Case reports show that malnourished, frail elderly, or patients with liver disease can develop acute liver failure even at standard doses (4 g/day). Therefore, reducing the maximum oral dose to 3 g/day (1 g three times daily) is recommended for those at risk, including patients with decompensated cirrhosis, especially for long-term use. This practice is based on expert consensus and case studies from UK liver units.

Low body weight alone is not a proven independent risk factor, but it may indicate underlying conditions warranting dose reduction. For patients with low weight, advanced age, or frailty, regular review of risks and benefits is advised. If a lower dose is prescribed, patients should be informed of the reason and cautioned about over-the-counter paracetamol-containing products.

Risk Factors for hepatotoxicity and inadvertent overdose of paracetamol – see Appendix 1 for further information:

- Dry body weight under 50kg (the definition of dry body weight is under the dosage table below)
- Elderly/frail
- Renal insufficiency
- Decompensated liver disease
- Chronic malnutrition or chronic dehydration
- Cachexia
- Chronic alcohol consumption or regular consumption of alcohol in excess of recommended amounts
- Long-term treatment with liver enzyme-inducing drugs

Recommended Oral Paracetamol Dosage in Adult patients WITH risk factors:

	Weight ≤ 40kg	**41 – 49kg**	**>50kg**
Oral dose	500mg four times a day	500mg – 1g three times a day	500mg – 1g four times a day
Maximum daily dose	Maximum 2g in 24 hours	Maximum 3g in 24 hours	Maximum 4g in 24 hours

Please note:

- Dry body weight should be used for patients on dialysis (i.e., the patient's weight immediately after dialysis, when excess fluid buildup has been removed and is the lowest weight the patient can achieve without developing symptoms of hypotension or hypovolemia).
- Always leave at least 4 hours between doses.

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- Irrespective of weight, if the patient's eGFR is less than 30ml/min/1.73m^2, the interval between doses must be a minimum of 6 hours.
- As with all analgesics, there should be a regular clinical review of paracetamol effectiveness, assessment of adverse effects and any potential risk factors. This is to reduce the high risk of developing acute liver failure.
- In all patients, the lowest dose which manages the patient's pain should be used.

Recommended Oral Paracetamol Dosage in Adult patients WITHOUT risk factors:

500mg – 1g every 4 – 6 hours as required
Maximum 4g in 24 hours

Clinical judgement should guide the dosing and adjustment of oral paracetamol in patients with risk factors. Consider the following:

Document an up-to-date weight
A weight from within the past 4 weeks or, depending on risk factors, weigh more regularly if needed.

Assess the patient for risk factors
If risk factors are present, REDUCE the maximum daily dose:
- A lower starting dose and/or reduced frequency of dosing may be appropriate.
- 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 the patient information leaflet.
- If recommending a dose reduction, monitor pain control and offer alternate management strategies if needed.

Check when oral paracetamol was last administered
Follow the correct dosage interval. Do not exceed four doses of paracetamol in 24 hours.

Creatinine clearance
Irrespective of weight, if the patient's creatinine clearance (or absolute glomerular filtration rate) is **less than 30mL/minute**, the interval between doses **MUST be at least 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.

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.

Use of Prokinetics (e.g., metoclopramide or domperidone) will enhance gastric emptying and may increase the rate of paracetamol absorption.
- A reduction in the amount or frequency of paracetamol dosing may be appropriate.

Anticoagulants
- The effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol, with increased risk of bleeding.
- Monitor international normalised ratio (INR).

Cholestyramine
- May reduce absorption of paracetamol if given within one hour of administration of paracetamol.
- The SPC for cholestyramine states 'patients should take other drugs at least one hour before or 4-6 hours after cholestyramine to minimise possible interference with their absorption'.

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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 (6g salt in a 4 g dose per 24 hours).

- Avoid effervescent preparations of paracetamol where possible, particularly in people with hypertension, heart failure, and renal failure.

Monitor liver function tests, where indicated.

In a care home setting

- Ensure that the outcome is recorded and monitored, also when using when required (PRN) analgesia.
- To assess paracetamol outcome, use a validated pain assessment tool for those who cannot communicate their pain needs.
- It is crucial that assessment and treatment of pain are undertaken routinely for all patients, regardless of the setting.
- Ensure clear dosage instructions and a minimum dosing interval are provided to the care home (each resident taking PRN medication must have a PRN care plan).
- Accurately record the paracetamol administration time to ensure that the appropriate time interval is given between doses.

Bibliography

1. British Hepatology Pharmacy Group (2022) Position statement: Prescribing weight-adjusted oral paracetamol in adults
2. Shropshire, Telford and Wrekin guideline for prescribing weight-adjusted oral paracetamol in adults, June 2022

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Appendix 1

Further information

Dry body weight under 50kg (The definition of dry body weight is under the dosage table above)

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 predispose them to liver damage from paracetamol. It should be remembered that 50kg is a relatively arbitrary threshold, and patients weighing more than this may also have conditions that warrant consideration of a dose reduction.

Elderly/frail

A reduction in 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 the risk of inadvertent paracetamol toxicity and overdose.

Decompensated liver disease

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

Chronic malnutrition or chronic dehydration

Consider reviewing patients who have not been eating or drinking for a few days. Consider reviewing patients with risk of renal impairment in cases of dehydration and acute kidney injury.

Cachexia

A multifactorial syndrome characterised by an ongoing loss of skeletal muscle mass that cannot be fully reversed by conventional nutritional support and that leads to progressive functional impairment.

Chronic alcohol consumption or regular consumption of alcohol in excess of recommended amounts

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

Long-term treatment with liver enzyme-inducing drugs

e.g. carbamazepine, phenytoin, primidone, rifampicin, phenobarbital, St John’s Wort or other drugs that induce liver enzymes.