Dosing: Neonatal

Fever:
Oral: Limited data available:
GA 28 to 32 weeks: 10 to 12 mg/kg/dose every 6 to 8 hours; maximum daily dose: 40 mg/kg/day (Anand 2001; Anand 2002)
GA 33 to 37 weeks or term neonates <10 days: 10 to 15 mg/kg/dose every 6 hours; maximum daily dose: 60 mg/kg/day (Anand 2001; Anand 2002)
Term neonates ≥10 days to 15 mg/kg/dose every 4 to 6 hours (Anand 2001; Anand 2002); do not exceed 5 doses in 24 hours; maximum daily dose: 75 mg/kg/day

IV:
GA 28 to <32 weeks: Limited data available: Note: Some experts do not recommend the use of IV acetaminophen in premature neonates <32 weeks. PMA until pharmacokinetic and pharmacodynamic studies have been conducted in this age group (van den Anker 2011).
Loading dose (Allegaert 2007; Bartocci 2007): 20 mg/kg/dose
Maintenance dose (Allegaert 2007; Allegaert 2011; Bartocci 2007): 10 mg/kg/dose every 12 hours; some suggest 7.5 mg/kg/dose every 8 hours; maximum daily dose: 22.5 mg/kg/day
GA ≥32 weeks:
Manufacturer’s labeling:
PMA 54 weeks: 12.5 mg/kg/dose every 6 hours; maximum daily dose: 50 mg/kg/day
PMA ≥4 weeks: 15 mg/kg/dose every 6 hours; maximum daily dose: 60 mg/kg/day
Alternate dosing:
Loading dose (Allegaert 2007; Bartocci 2007): 20 mg/kg/dose
Maintenance dose (Allegaert 2007; Allegaert 2011; Bartocci 2007): 30 mg/kg/dose every 12 hours; some suggest 7.5 mg/kg/dose every 8 hours; maximum daily dose: 22.5 mg/kg/day
PMA 33 to 36 weeks: 10 mg/kg/dose every 8 hours; some suggest 7.5 to 10 mg/kg/dose every 6 hours; maximum daily dose: 40 mg/kg/day
PMA ≥37 weeks: 10 mg/kg/dose every 6 hours; maximum daily dose: 40 mg/kg/day

Rectal: Limited data available:
GA 28 to <32 weeks: 20 mg/kg/dose every 12 hours; maximum daily dose: 40 mg/kg/day (Anand 2001; Anand 2002)
GA 33 to 37 weeks or term neonates <10 days:
Loading dose: 30 mg/kg; then 15 mg/kg/dose every 8 hours; maximum daily dose: 60 mg/kg/day (Anand 2001; Anand 2002)
Term neonates ≥10 days: 10 to 15 mg/kg/dose every 4 to 6 hours (Anand 2001; Anand 2002); do not exceed 5 doses in 24 hours; maximum daily dose: 75 mg/kg/day

Pain: Limited data available:
Oral:
GA 28 to 32 weeks: 10 to 12 mg/kg/dose every 6 to 8 hours; maximum daily dose: 40 mg/kg/day (Anand 2001; Anand 2002)
GA 33 to 37 weeks or term neonates <10 days:
Loading dose: 30 mg/kg; then 15 mg/kg/dose every 8 hours; maximum daily dose: 60 mg/kg/day (Anand 2001; Anand 2002)
Term neonates ≥10 days: 10 to 15 mg/kg/dose every 4 to 6 hours (Anand 2001; Anand 2002); do not exceed 5 doses in 24 hours; maximum daily dose: 75 mg/kg/day

IV:
Efficacy results variable; optimal dose not established: Note: Some experts do not recommend the use of IV acetaminophen in premature neonates <32 weeks. PMA until pharmacokinetic and pharmacodynamic studies have been conducted in this age group (van den Anker 2011).
Loading dose (Allegaert 2007; Bartocci 2007): 20 mg/kg/dose
Maintenance dose (Allegaert 2007; Allegaert 2011; Bartocci 2007): 10 mg/kg/dose every 12 hours; some suggest 7.5 mg/kg/dose every 8 hours; maximum daily dose: 22.5 mg/kg/day
PMA 33 to 36 weeks: 10 mg/kg/dose every 8 hours; some suggest 7.5 to 10 mg/kg/dose every 6 hours; maximum daily dose: 40 mg/kg/day
PMA ≥37 weeks: 10 mg/kg/dose every 6 hours; maximum daily dose: 40 mg/kg/day

Rectal:
GA 28 to 32 weeks: 20 mg/kg/dose every 12 hours; maximum daily dose: 40 mg/kg/day (Anand 2001; Anand 2002)
GA 33 to 37 weeks or term neonates <10 days:
Loading dose: 30 mg/kg; then 15 mg/kg/dose every 8 hours; maximum daily dose: 60 mg/kg/day (Anand 2001; Anand 2002)
Term neonates ≥10 days: 10 to 15 mg/kg/dose every 4 to 6 hours (Anand 2001; Anand 2002); do not exceed 5 doses in 24 hours; maximum daily dose: 75 mg/kg/day

Acetaminophen Dosing (Oral)

Weight (preferred)** Age Dosage (mg)

<table>
<thead>
<tr>
<th>kg</th>
<th>lbs</th>
<th>0 to 3 mo</th>
<th>4 to 11 mo</th>
<th>1 to 2 y</th>
<th>2 to 3 y</th>
<th>3 to 4 y</th>
<th>4 to 5 y</th>
<th>5 to 6 y</th>
<th>6 to 8 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3.5</td>
<td>4.3-6.7</td>
<td>6-28</td>
<td>11-70</td>
<td>160</td>
<td>130</td>
<td>110</td>
<td>90</td>
<td>70</td>
<td>60</td>
</tr>
<tr>
<td>7-10.5</td>
<td>15.4-23</td>
<td>12-28</td>
<td>28-75</td>
<td>500</td>
<td>450</td>
<td>400</td>
<td>370</td>
<td>320</td>
<td>300</td>
</tr>
</tbody>
</table>

**Manufacturer’s recommendations are based on weight in pounds and kg. Ceiling weight in kg listed here is derived from pounds and rounded; kg weight listed also is adjusted to nearest achievable weight in kg. OTC labeling instructs consumer to consult with physician for dosing in infants and children under 2 years of age.

Immediate release solid dosage formulations:
Note: Actual OTC dosing recommendations may vary by product and/or manufacturer:
Children 6 to 11 years: 325 mg every 4 to 6 hours; maximum daily dose: 1,625 mg/day; Note: Do not use more than 5 days unless directed by a physician.
Children 12 years and Adolescents:
Regular strength: 650 mg every 4 to 6 hours; maximum daily dose: 3,250 mg/day unless needed by a physician under physician supervision daily doses ≤4,000 mg may be used
Extra strength: 1,000 mg every 6 hours; maximum daily dose: 3,000 mg/day unless directed

Dosing: Usual Note: In 2011, McNeil Consumer Healthcare reduced the maximum daily doses and increased the dosing interval on the labeling of some of their acetami

Dosing: Usual Note: Limit acetaminophen OTC products used in older pediatric patients (usually children ≥12 years and adolescents), and adults in an attempt to protect consumers from inadvertent overdoses. For example, the maximum daily dose of Extra Strength Tylenol OTC and Regular Strength Tylenol OTC were increased to 3,000 mg/day and 3,250 mg/day respectively, and the dosing interval for Extra Strength Tylenol OTC was increased. Health care professionals may still prescribe or recommend the 4 adult daily maximum to patients ≥12 years of age (but are advised to use their own discretion and clinical judgment) (McNeil Consumer Healthcare 2014).

Pediatric:
Oral liquids are available in multiple concentrations (eg, 160 mg/5 mL, 500 mg/5 mL and 500 mg/15 mL); precautions should be taken to verify and avoid confusion between the different concentra
tions; doses should be clearly presented as “mg”.

Pain (mild to moderate) or fever: Note: Limit acetaminophen from all sources (prescription and OTC); maximum daily dose to children, infants and adolescents should be limited to ≤75 mg/kg/day in ≤5 divided doses and not to exceed 4,000 mg/day for most products although some formulations suggest lower maximum daily dosing (see dosing information for further detail):

Oral: With OTC use, should not exceed recommen
ted treatment duration unless directed by health care provider; for fever: 3 days (all ages); pain (excluding sore throat): Children ≥12 years and ado
elscents: 10 days, children, 5 days; infants: 3 days; some suggest 7.5 to 10 mg/kg/dose every 6 hours; maximum daily dose: 22.5 mg/kg/day

Sore throat in children: 2 days

With OTC dosing: Infants, Children, and Ado
elscents: 10 to 15 mg/kg/dose every 4 to 6 hours as needed (American Pain Society 2008; Kliegman 2011; Sullivan 2011); do not exceed 5 doses in 24 hours; maximum daily dose: 75 mg/kg/day not to exceed 4,000 mg/day

Fixed dosing:
Oral suspension, chewable tablets: Infants and Chil

dren <12 years: Consult specific product formula
tions for appropriate age groups. See table; use of weight to select dose is preferred; if weight is not available, then use age; doses may be repeated every 4 hours; maximum: 5 doses/day

Rectal:
GA 28 to 32 weeks: 20 mg/kg/dose every 12 hours; maximum daily dose: 40 mg/kg/day (Anand 2001; Anand 2002)
GA 33 to 37 weeks or term neonates <10 days:
Loading dose: 30 mg/kg; then 15 mg/kg/dose every 8 hours; maximum daily dose: 60 mg/kg/day (Anand 2001; Anand 2002)
Term neonates ≥10 days: 10 to 15 mg/kg/dose every 4 to 6 hours (Anand 2001; Anand 2002); do not exceed 5 doses in 24 hours; maximum daily dose: 75 mg/kg/day

by a physician; under physician supervision daily dosing may be used.

Extended release: Children ≥12 years and Adolescents: 1,300 mg every 8 hours; maximum daily dose: 3,900 mg/day

IV.

Infants and Children <2 years:

Manufacturer’s labeling: Fever: 15 mg/kg/dose every 6 hours; maximum daily dose: 60 mg/kg/day

Alternate dosing: Limited data available: Pain: fever: 7.5 to 15 mg/kg/dose every 6 hours; maximum daily dose: 60 mg/kg/day (Wilson-Smith, 2009).

Children ≥2 years and Adolescents:

<50 kg: 15 mg/kg/dose every 6 hours or 12.5 mg/kg/dose every 4 hours; maximum single dose: 15 mg/kg, up to 750 mg; maximum daily dose: 75 mg/kg/day not to exceed 3,750 mg/day ≥50 kg: 1,000 mg every 6 hours or 650 mg every 4 hours; maximum single dose: 1,000 mg; maximum daily dose: 4,000 mg/day

Rectal:

Weight-directed dosing: Limited data available: Infants and Children <12 years: 10 to 20 mg/kg/dose every 4 to 6 hours as needed; do not exceed 5 doses in 24 hours (Kliegman 2011; Vernon 1979); maximum daily dose: 75 mg/kg/day

Parental dosing:

Infants 6 to 11 months: 80 mg every 6 hours; maximum daily dose: 320 mg/day

Infants and Children 12 to 36 months: 80 mg every 4 to 6 hours; maximum daily dose: 400 mg/day

Children ≥3 to 6 years: 120 mg every 4 to 6 hours; maximum daily dose: 600 mg/day

Children >6 to 12 years: 325 mg every 4 to 6 hours; maximum single dose: 1,625 mg/day

Children ≥12 years and Adolescents: 650 mg every 4 to 6 hours; maximum daily dose: 3,900 mg/day

Pain; peri-/postoperative management; adjunct to opioid therapy:

IV.

Infants and Children <2 years: Limited data available: 7.5 to 15 mg/kg/dose every 6 hours; maximum daily dose: 60 mg/kg/day (Wilson-Smith, 2009)

Children ≥2 years and Adolescents:

<50 kg: 15 mg/kg/dose every 6 hours or 12.5 mg/kg/dose every 4 hours; maximum single dose: 15 mg/kg, up to 750 mg; maximum daily dose: 75 mg/kg/day not to exceed 3,750 mg/day ≥50 kg: 1,000 mg every 6 hours or 650 mg every 4 hours; maximum single dose: 1,000 mg; maximum daily dose: 4,000 mg/day

Rectal:

Limited data available: Children and Adolescents:

Fever: 15 mg/kg/dose every 6 hours or 12.5 mg/kg/dose every 4 hours; maximum single dose: 15 mg/kg up to 750 mg; maximum daily dose: 75 mg/kg/day (Wilson-Smith, 2009).

Infants, Children, and Adolescents:

GFR ≥10 mL/minute/1.73 m²: No adjustment required

GFR <10 mL/minute/1.73 m²: Administer every 8 hours

Intermittent hemodialysis or peritoneal dialysis: Administer every 8 hours

CRRT: No adjustments necessary

Adults:

CrCl 10 to 50 mL/minute: Administer every 6 hours

CrCl <10 mL/minute: Administer every 8 hours

Intermittent hemodialysis or peritoneal dialysis: No adjustment necessary

CRRT: Administer every 6 hours

Dosing adjustment in renal impairment:

IV.

Children <2 years, Adolescents, and Adults: CrCl ≤30 mL/minute: Use with caution; consider decreasing daily dose and extending dosing interval

Oral (Arrington 2007):

Infants, Children, and Adolescents:

GFR ≤10 mL/minute/1.73 m²: No adjustment required

GFR <10 mL/minute/1.73 m²: Administer every 8 hours

Preparation for Administration

Parenteral: Injectable solution may be administered directly from the vial without further dilution. Use within 6 hours of opening vial or transferring to another container. Discard any unused portion; single-use vials only.

Dosages <1,000 mg (<50 kg): Withdraw appropriate dose from storage vial and transfer to a separate sterile container (eg, glass bottle, plastic IV container, syringe) for administration. Small volume pediatric doses (up to 600 mg [60 mL]) may be placed in a syringe.

Dosages of 1,000 mg (≥50 kg): Insert vented IV set through vial stopper.

Administration

Oral: Administer with food to decrease GI upset; shake drops and suspension well before use; do not crush or chew extended release products

Parenteral: For IV infusion only. May administer undiluted over 15 to 30 minutes. Use up to 6 hours of opening vial or transferring to another container. Discard any unused portion; single-use vials only.

Rectal: Remove wrapper; insert suppository well up into the rectum.

Test Interactions

Acetaminophen may cause false-positive urinary 5-hydroxyindoleacetic acid.

Additional Information

Tylenol: 325 mg

Pain Eze: 650 mg

Mapap Extra Strength: 500 mg

Omnopon: 750 mg

Pepcid: 25 mg

ADAM: 1,300 mg

OxyContin: 15 mg

Durogesic: 25 mg

Oxymorphone: 2 mg

Narcan: 0.4 mg

Naloxone: 0.4 mg

Ave Paracetamol: 325 mg

Diphenoxylate: 2 mg

Codeine Phosphate: 30 mg

Hydrocodone: 10 mg

OxyContin ER: 20 mg

Oxycodone: 10 mg

Morphine: 10 mg

Fentanyl: 0.5 mg

Ketalar: 50 mg

Ketamine: 100 mg

Dilaudid: 2 mg

Dilaudid: 5 mg

Demerol: 50 mg

Demerol: 100 mg

Dexmedetomidine: 0.2 mg

5 mg

Acetaminophen may cause false-positive urinalysis 5-hydroxyindoleacetic acid.

Additional Information

Propacetamol (pro-drug) = 1 mg paracetamol = 1 mg acetaminophen

Acetaminophen (15 mg/kg/dose given orally every 6 hours for 24 hours) did not relieve the intraoperative and the immediate postoperative pain associated with neonatal circumcision; some benefit was seen 6 hours after circumcision (Howard, 1994).

There is currently no scientific evidence to support alternate acetaminophen with ibuprofen in the treatment of circumcision (Mayoral, 2000).

Based on recommendations provided by the Food and Drug Administration (FDA), all liver-to-counter (OTC) pediatric single-ingredient acetaminophen liquid products are now only available as a single concentration of 160 mg/5 mL; the transition began in 2011. The concentration 80 mg/0.8 mL is no longer available in the US. The recommended mg/kg dose is unaffected.

Product Availability

Ofimev 100 mL IV bag formulation: FDA approved November 2016; availability anticipated in the second quarter of 2017.

Dosage Forms

Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

[DSC] = Discontinued product

Caplet, oral: 500 mg

Cetafen Extra: 500 mg

Mapap Extra Strength: 500 mg

Mapap Extra Strength: 500 mg [scored]

Pain Eze: 650 mg

Tylenol: 325 mg

Tylenol Extra Strength: 500 mg

ACETAMINOPHEN