



## TOOL 6.3: Approved Medications for Pediatric Indications

Medications may be used as indicated or as off-label use for symptoms related to features of concussion (i.e., migraine headache, muscular discomfort, sleep, cognitive, and mood disorders) or for patients with an acute or prolonged concussion who also have co-existing medical diagnoses that may have been prescribed medications for other indications.

Use clinical judgment and discretion at all times when prescribing medication.

Drug	Health Canada Approval	FDA Approval	Dosage#
<b>Headache or Muscular Strain</b>			
> <b>Acetaminophen</b>	Treatment of mild/moderate pain and fever. All ages.	All ages for mild to moderate pain and fever	10-15 mg/kg/dose orally/rectal every 4h as needed (maximum 75 mg/kg/day or 4,000 mg/day)
> <b>Ibuprofen</b>	Pediatric patients for mild to moderate pain. Fever in pediatric patients.	Mild to moderate pain in patient's $\geq 6$ months old. Reduction in fever in patient's $\geq 6$ months old. Juvenile arthritis in pediatric patients.	5-10 mg/kg/dose orally every 6-8h as needed (max 600 mg/dose or 40 mg/kg/day)
> <b>Naproxen</b>	Children $\geq 2$ years of age: 1) osteoarthritis, ankylosing spondylitis, juvenile rheumatoid arthritis 2) aches/pains and mild to moderate pain due to sprains/strains 3) primary dysmenorrhea	> 2 years of age for analgesia, inflammatory disease	5 mg/kg/dose orally twice daily. Max 500 mg/dose, 1,000 mg/day (usual adult dose: 250-500 mg)
<b>Migraine Headache</b>			
> <b>Amitriptyline</b>	None	None	Chronic pain: 0.1 mg/kg, increase as needed to 0.5-2 mg/kg (off label dosing)
> <b>Diclofenac powder for oral suspension (Cambia®)</b>	No indication <18 years of age. Acute treatment of migraine attacks with or without aura in adults 18 years of age or older.	No indication <18 years of age. Acute treatment of migraine attacks with or without aura in adults 18 years of age or older.	Adult: 50 mg q24 hrs prn (max 15 doses/ month). *Note: the safety of taking a second dose has not been studied, as per the manufacturer.
> <b>Triptan (example: rizatriptan, sumatriptan)</b>	Almotriptan: acute treatment of migraine headache with or without aura in patients 12-17 years of age. Naratriptan: None Rizatriptan: None Sumatriptan: None Zolmitriptan: None	Almotriptan: acute treatment of migraine headache with or without aura in patients 12-17 years of age. Naratriptan: None Rizatriptan: > 6 years of age for acute treatment of migraine with or without aura Sumatriptan: None Zolmitriptan: None	Almotriptan: 6.25-12.5 mg, may repeat dose after 2 hours if needed (max 25 mg/day) Rizatriptan: $\leq 40$ kg: 5 mg/24 hrs, $\geq 40$ kg: 10 mg/24 hrs

Tool 6.3: Approved Medications for Pediatric Indications (cont'd)

Drug	Health Canada Approval	FDA Approval	Dosage#
> <b>Beta-blockers- Propranolol</b>	migraine prophylaxis	Adult-approved indication for migraine	0.5-4 mg/kg/day
> <b>Topiramate</b>		Adult- approved prevention of migraine headaches	2-16 years: initial dose: 1-3 mg/kg/day orally, increase every 1-2 weeks by 1-3 mg/kg/day divided twice per day. Maintenance dose 5-9 mg/kg/day divided twice per day. ≥ 17 yrs. 50 mg daily. Increase each week by 50 mg/day. Max dose 600 mg/day (Off label dosing)
<b>Sleep Disorders</b>			
> <b>Trazodone</b>	None	None	
> <b>Zopiclone</b>	None	None	
> <b>Magnesium Oxide</b>	Classified as a natural health product. For hypomagnesemia/dietary supplement. No age restrictions.	Magnesium supplement. No age restriction.	20-40 mg/kg/day
> <b>Melatonin</b>	Licensed Natural Health product –no Health Canada monograph	None	0.5-3 mg every night at bedtime (Max. 12 mg)
> <b>Zinc</b>	Licensed Natural Health Product – no Health Canada monograph	Treatment and prevention of zinc deficiency states.	Recommended dietary allowance: infants 5 mg/day, 1-10 years: 10 mg/day, > 11 years: 12-15 mg/day
> <b>Tryptophan</b>	None	None	
<b>Mood Disorders</b>			
> <b>Fluoxetine</b>	none	Major depressive disorder (≥ 8 years) Obsessive compulsive disorder (≥ 7 years)	Major depressive disorder: 10-20 mg/day Obsessive compulsive disorder: 10-30 mg/day. Up to 60 mg/day in higher weight children/ adolescents
> <b>Sertraline</b>	None	Obsessive-compulsive disorder (≥ 6 years)	6-12 years: 25 mg daily, increase as needed to a max of 200 mg/day 13-17 years: 50 mg/day, increase as needed to 200 mg
> <b>Fluvoxamine</b>	None	Obsessive-compulsive disorder (≥ 8 years)	8-17 years: 25 mg daily, increase as needed to a max of 200 mg in 8-11 years and 300 mg/day in adolescents
> <b>Paroxetine</b>	None	None	

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Drug	Health Canada Approval	FDA Approval	Dosage#
> <b>Citalopram</b>	None	None	
> <b>Escitalopram</b>	None	Major depressive disorder ≥ 12 years	10 mg daily, increase as needed to a max of 20 mg
> <b>Duloxetine</b>	None	Generalized Anxiety Disorder: 7-17 years	Starting dose: 30mg daily Recommended dose: 30mg daily; max dose: 120mg daily
> <b>Venlafaxine</b>	None	None	
> <b>Mirtazapine</b>	None	None	
> <b>Lurasidone</b>	Depressive episodes associated with bipolar I disorder: 13-17 years Schizophrenia: 15-17 years	Depressive episodes associated with bipolar I disorder: 10-17 years Schizophrenia: 13-17 years	Bipolar I depression starting dose: 20mg po daily; recommended dose 20mg-80mg daily. Schizophrenia starting dose: 40mg daily; recommended dose: 40mg-80mg daily
> <b>Prochlorperazine</b>	≥ 2 years for or > 9 kg 1) psychotic disorders (agitation, confusion, delusion, tension, and anxiety) 2) nausea and vomiting 3) relief of excessive anxiety associated with psychoneurotic or somatic conditions	≥ 2 years or children > 9 kg for 1) nonsurgical nausea and vomiting 2) psychosis	Antiemetic: 0.4 mg/kg/day Psychosis: 2.5 mg orally increase as needed to 20 mg/day (off label dosing)
<b>Cognitive Problems</b>			
> <b>Methylphenidate, extended release (Concerta®, Biphentin®)</b>	Treatment of ADHD in children 6 years of age and older.	Treatment of ADHD in children 6 years of age and older for Concerta® only; Biphentin® not marketed in the USA.	<b>Concerta®</b> Children and adolescents: Initial - 18mg once a day. Increase daily dose by 18 mg at weekly intervals. Maximum of 54 mg in children and 72 mg in adolescents.  <b>Biphentin®</b> Children and adolescents: Initial - 10-20 mg once daily. Increase daily dose by 10 mg/day at weekly intervals. Typical maximum of 60 mg/day. However, manufacturer states in some children, higher doses up to a maximum of 1 mg/kg/day may be necessary.

Tool 6.3: Approved Medications for Pediatric Indications (cont'd)

Drug	Health Canada Approval	FDA Approval	Dosage#
> Concerta (OROS Methyphenidate Hydrochloride)	ADHD	ADHD	Children and adolescents between 6-18 years old. Starting dose: 18mg po qAM, with increases weekly as needed and as tolerated to a max of 54mg.
>Dextroamphetamine (Dexedrine®)  Dextroamphetamine, sustained release (Dexedrine Spansules®)	Treatment of ADHD and in the adjunctive treatment of narcolepsy in children 6 years of age and older.	Treatment of ADHD and in the adjunctive treatment of narcolepsy in children 6 years of age and older.	<i>ADHD</i> Children 6 years of age or older: Initial - 5 mg once or twice daily. Increase the daily dose by 5 mg at weekly intervals. *Dexedrine Spansules® may be used for once-a-day dosing where appropriate.  Typical maximum of 40 mg/day, but may go up to 60 mg/day if needed.  <i>Narcolepsy</i> Children 6-12 years: Initial- 5 mg daily. Increase daily dose by 5 mg at weekly intervals. Maximum of 60 mg/day. Adolescents 12 years or older: Initial - 10 mg daily. Increase daily dose by 10 mg at weekly intervals. Maximum of 60 mg/day.
> Lisdexamphetamine (Vyvanse®)	Treatment of ADHD in children 6 years of age and older.	Treatment of ADHD in children 6 years of age and older.	Children and adolescents: Initial – 20-30 mg once a day in the morning. Increase daily dose by 10-20 mg at weekly intervals. Max of 60 mg/day (Canada). Max of 70 mg/day (US).
> Clonidine (Catapres®)	No indication <18 years of age. No approved indications for ADHD at any age.  Used off-label in children 6 years of age and older for ADHD treatment as monotherapy or adjunctive to stimulant medications.	Extended-release clonidine (Kapvay®) approved for ADHD treatment in children 6 years of age and older.  *note: extended-release clonidine is not available in Canada.	Off label dosing: Children less than 45 kg: Initial – 0.05 mg at bedtime. Increase every 3-7 days in 0.05 mg/day increments given as 0.05 mg BID, then TID, then QID. Maximum daily dose for 27-40.5 kg = 0.2 mg/day. Maximum daily dose for 40.5-45 kg = 0.3 mg/day.  Children and adolescents greater than 45 kg: Initial – 0.1 mg at bedtime. Increase every 3-7 days in 0.1 mg/day increments given as 0.1 mg BID, then TID, then QID. Max daily dose of 0.4 mg/day.

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Drug	Health Canada Approval	FDA Approval	Dosage#
> <b>Amphetamine Mixed Salts, extended-release (Adderall XR®)</b>	Treatment of ADHD in children 6 years of age and older.	Treatment of ADHD in children 6 years of age and older.	<p>Children 6-12 years of age: Initial – 5-10 mg daily in the morning. Increase daily dose by 5-10 mg at weekly intervals. Maximum of 30 mg/day.</p> <p>Adolescents 13-17 years of age: Initial – 10 mg once a day in the morning. Increase daily dose by 5-10 mg at weekly intervals. Maximum of 30 mg/day.</p>
> <b>Atomoxetine (Strattera®)</b>	Treatment of ADHD in children 6 years of age and older.	Treatment of ADHD in children 6 years of age and older.	<p>Children up to 70 kg: Initial: 0.5 mg/kg/day for 7-14 days. If tolerated, increase to 0.8 mg/kg/day for 7-14 days, then increase to 1.2 mg/kg/day given once daily or divided BID. Maximum 1.4 mg/kg/day or 100 mg, whichever is less.</p> <p>Adolescents greater than 70 kg: Initial – 40 mg/day for 7-14 days. If tolerated, increase to 60 mg/day for 7-14 days, then increase to 80 mg/day given once daily or divided BID. Maximum 100 mg/day.</p>
> <b>Guanfacine, extended-release (Intuniv XR®)</b>	Monotherapy or as adjunctive to stimulant medications for the treatment of ADHD in children 6 years of age and older.	Monotherapy or as adjunctive to stimulant medications for the treatment of ADHD in children 6 years of age and older.	<p>Children 6-12 years of age: Initial – 1 mg once daily. Increase daily dose by 1 mg at weekly intervals. Maximum of 4 mg/day.</p> <p>Adolescents 13-17 years of age: Initial – 1 mg once daily. Increase daily dose by 1 mg at weekly intervals. Maximum of 7 mg/day for monotherapy, or 4 mg/day for adjunctive therapy to stimulants.</p>

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Drug	Health Canada Approval	FDA Approval	Dosage#
> Amantadine	No indications less than 18 years of age for ADHD.	No indication less than 18 years of age for ADHD.	(off label use in children 5 years of age and older as an adjunctive agent to stimulants for ADHD treatment, and to target irritability and hyperactivity in ASD)  ADHD Children 5 years of age and older: Initial – 50 mg/day. Increase daily dose by 50 mg at 4-7 day intervals. Typical range: 50-150 mg/day in divided doses 1-3 times daily. Maximum of 100 mg/day in children less than 30 kg. Maximum of 150 mg/day in children and adolescents 30 kg and greater.

Abbreviations: Attention deficit hyperactivity disorder (ADHD), autism spectrum disorder (ASD); Per os (po); bis in die (two times a day- BID); hour (h); IV (intravenous); omne in die -once a day (od); every morning (qAM); ter in die- three times a day (TID); as needed dosing (prn).

Dosages from Sick Kids 2013/2014 Drug Handbook and Formulary, Lexicomp Pediatric Dosage Handbook 19th Edition, CHEO Pediatric Doses of Commonly Prescribed Medications 2011, <https://www.accessdata.fda.gov/scripts/cder/daf/>, Clinical Handbook of Psychotropic Drugs for Children and Adolescents, 4th ed. 2019.

