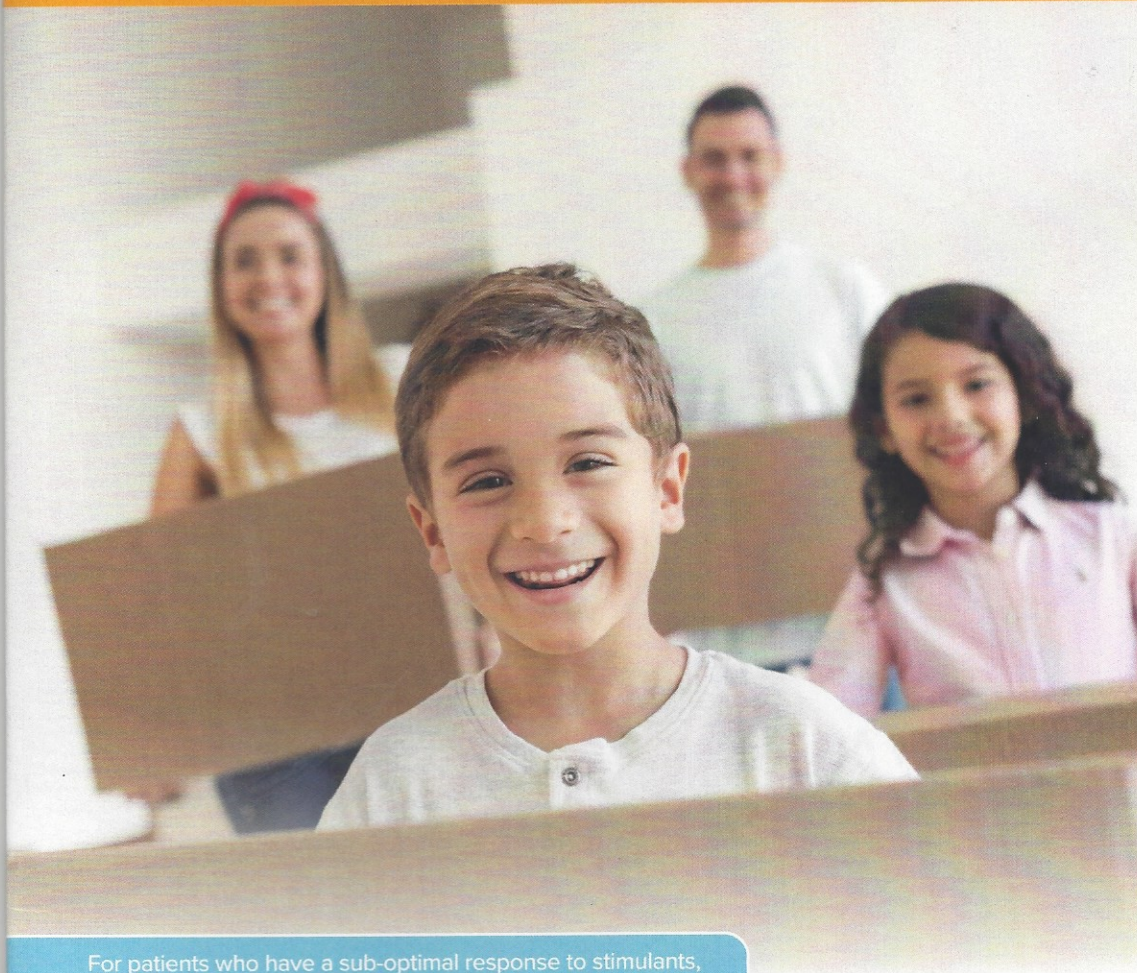


INTUNIV XR is the **first and only** adjunctive medication in Canada indicated for the treatment of ADHD in children and adolescents aged 6–17 years.¹



For patients who have a sub-optimal response to stimulants, consider **INTUNIV XR** as adjunctive therapy.

FINDING THE OPTIMAL DOSE OF INTUNIV XR FOR YOUR ADHD PATIENTS BASED ON A DOSE-OPTIMIZATION STUDY

INTUNIV XR can also be used as monotherapy¹

INTUNIV XR (guanfacine hydrochloride extended-release tablets) is indicated as adjunctive therapy to psychostimulants for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents, aged 6 to 17 years, with sub-optimal response to psychostimulants. INTUNIV XR is also indicated as monotherapy for the treatment of ADHD in children and adolescents aged 6 to 17 years.¹

ADHD: attention deficit hyperactivity disorder



ONCE-DAILY DOSING WITH INTUNIV XR¹

can be given either



MORNING

OR







EVENING

Administration considerations:

- INTUNIV XR should not be crushed, chewed, or broken before swallowing
- INTUNIV XR should not be administered with high-fat meals

Titrate gradually based on clinical response and tolerability¹

START with 1 mg once daily for adjunctive and monotherapy use	 1 mg		
TITRATE 1 mg at a time, with 1 week or more between dose changes	 2 mg	 3 mg	 4 mg
Up to maximum daily dose of:	Adjunctive therapy	4 mg/day	6–17 years
	Monotherapy	4 mg/day	6–12 years
		7 mg/day	13–17 years
The weight-based target dose range for INTUNIV XR is 0.05–0.12 mg/kg/day.*			

REMEMBER: Since the dose may need to be adjusted until it is appropriate for the patient, it may take some time to see the full treatment effect of INTUNIV XR.¹

Guanfacine hydrochloride extended-release tablets (INTUNIV XR) are recommended by CADDRA for patients with ADHD as monotherapy and as an adjunctive therapy to psychostimulants.²

* Doses above 4 mg/day have not been evaluated in children (ages 6–12 years) and doses above 7 mg/day have not been evaluated in adolescents (ages 13–17 years).

Doses above 4 mg should be administered as combinations of the dose strengths shown here.

Please consult the Product Monograph for complete dosing and administration recommendations.



ADJUNCTIVE DOSE-OPTIMIZATION STUDY OF INTUNIV XR IN 6- TO 17-YEAR-OLDS³

In a double-blind, placebo-controlled, dose-optimization study, children and adolescents 6–17 years old continued their stable dose of morning psychostimulant and were randomized to receive INTUNIV XR in the morning or evening, or placebo*

INTUNIV XR + stimulant (vs. stimulant alone) **demonstrated 31% ADHD symptom improvement** when dosed in the evening (ADHD-RS-IV score; -21.0 vs. -16.0, respectively; $p < 0.001$; baseline values were 37.0 and 37.7, respectively)³

Reported doses of INTUNIV XR after 9 weeks

EVENING INTUNIV XR + PSYCHOSTIMULANT	
Mean dose [†]	3.2 mg/day
% of patients receiving	
1 mg/day	5.3%
2 mg/day	17.8%
3 mg/day	23.0%
4 mg/day	43.4%

Adapted from Wilens TE et al.³

Discontinuation considerations:¹

Patients should be advised not to discontinue INTUNIV XR without consulting their physician. If discontinuing therapy, taper in decrements of no more than 1 mg every 3–7 days to minimize the risk of an increase in blood pressure upon discontinuation. Patients should be monitored during downward titration and following discontinuation, until blood pressure and heart rate have returned to baseline.

* Treated with INTUNIV XR + stimulant in the morning (n=150) or evening (n=152), or placebo + stimulant (n=153).

[†] Doses above 4 mg/day have not been studied in adjunctive trials.

INTUNIV XR is covered on the **Ontario Drug Benefit** formulary (limited use)⁴ and listed on **RAMQ** List of Medications as an exception drug⁵

Ontario

LU code 540: For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 6 to 17 years who meet the following criteria:

- i. As adjunctive therapy to psychostimulants; OR
- ii. As monotherapy in patients who have significant intolerance to psychostimulants AND who have had an inadequate response to either atomoxetine or other non-stimulant alternative(s).

Quebec

RAMQ criteria:

- In combination with a psychostimulant for the treatment of children and adolescents with attention deficit disorder with or without hyperactivity, in whom it is not possible to obtain good control of symptoms of their condition with methylphenidate and an amphetamine when used as monotherapy.
- Before it can be concluded that the effectiveness of these drugs is sub-optimal, they must have been titrated at optimal doses.

Clinical use:

INTUNIV XR is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational/vocational, social) for patients with this syndrome. The physician electing to use INTUNIV XR for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient. INTUNIV XR is not indicated in children <6 years of age and in patients ≥18 years of age.

Contraindications:

- History of hypersensitivity to this drug, to any ingredient in the formulation or component of the container, or to any other product containing guanfacine

Relevant warnings and precautions:

- Somnolence and sedation
- Hypotension, bradycardia, and syncope
- Elevated blood pressure and heart rate upon discontinuation
- QTc interval increase
- Pre-existing psychosis, screening patients for bipolar disorder, emergence of new psychotic or manic symptoms, aggression, and suicidal behaviour and ideation

- Patients with hepatic or renal impairment
- Monitoring of heart rate and blood pressure
- Advise patients to avoid dehydration or becoming overheated
- Caution in patients treated with CYP3A4 and CYP3A5 inhibitors, and CYP3A4 inducers

For more information:

Please consult the Product Monograph at www.takeda.com/en-ca/intuniv-xr-pm for important information relating to adverse reactions, drug interactions, and dosing information that have not been discussed in this piece. The Product Monograph is also available by calling Shire Pharma Canada ULC at 1-800-268-2772.

References: 1. Intuniv XR Product Monograph. Shire Pharma Canada ULC. January 23, 2019. 2. Canadian ADHD Resource Alliance (CADDRA): Canadian ADHD Practice Guidelines, 4th ed. Toronto, ON: CADDRA; 2018. 3. Wilens TE, et al. A controlled trial of extended-release guanfacine and psychostimulants for attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2012;51(1):74-85.e72. 4. Ontario Drug Benefit formulary. Available at: www.formulary.health.gov.on.ca/formulary/. 5. RAMQ (official mark of the Régie de l'assurance maladie du Québec) Lists of Medications. Available at: www.ramq.gouv.qc.ca/en/publications/citizens/legal-publications/Pages/list-medications.aspx. Retrieved March 4, 2020.

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intunivXR
(guanfacine hydrochloride) Extended-Release Tablets
1mg, 2mg, 3mg, 4mg