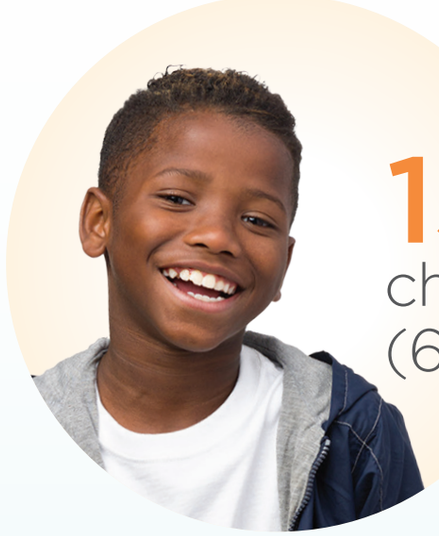
FOQUEST®
METHYLPHENIDATE HYDROCHLORIDE
CONTROLLED RELEASE CAPSULES

Guideline-recommended **first-line** for the treatment of children, adolescents, and adults with ADHD[1]

ARE YOU AWARE OF FOQUEST®'S CLINICAL SAFETY DATA?

1031 ADHD patients have been evaluated across four FOQUEST® clinical trials[2]



156
children
(6-12 years)

293
adolescents
(12-17 years)

582
adults

FOQUEST® (methylphenidate hydrochloride controlled release capsules) is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥6 years of age.[2]

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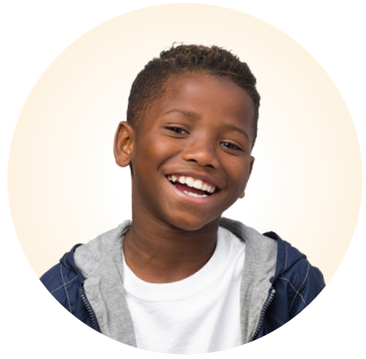
FOQUEST® SAFETY PROFILE

Adverse events (AEs) observed with FOQUEST® mainly reflect those commonly associated with methylphenidate use[2]



Children (6-12 years of age)

Very common treatment-emergent adverse events reported by ≥1% of children with ADHD in a laboratory classroom study with an up to 6-week open-label titration phase, followed by a 1-week double-blind treatment phase[2]*

	Open-label dose optimization phase (up to 6 weeks)	**Double-blind phase** (1 week)	
	FOQUEST®	**FOQUEST®**	**Placebo**
Headache	10.9% (17/156)	2.7% (2/83)	0
Insomnia	10.3% (16/156)	NR	NR
Decreased appetite	35.3% (55/156)	1.3% (1/83)	0
Abdominal pain	16.7% (26/156)	1.3% (1/83)	0

Adapted from FOQUEST® product monograph.
NR=not reported.

* Randomized, double-blind, placebo-controlled, parallel-arm, fixed-dose, multicentre trial measuring the efficacy and safety of FOQUEST® once daily in children aged 6-12 who met the DSM-5 criteria for ADHD. Following a washout period, children (n=156) entered an open-label dose optimization period of up to 6 weeks in which they were given 25 mg once daily in the morning to start, thereafter titrated once weekly from 25 mg to 35 mg to 45 mg to 55 mg to 70 mg to 85 mg FOQUEST® until an optimal dose was reached. Subjects (n=147) then entered 1-week of randomized double-blind treatment with placebo (n=75) or FOQUEST® capsules (n=73) at the optimized dose. (Note, the maximum recommended daily dose of FOQUEST® is 70 mg in children 6 to <18 years of age.[1]) At the end of the week, investigators evaluated attention and behaviour of subjects in a laboratory classroom setting using the SKAMP rating scale. The primary efficacy endpoint was the difference between FOQUEST® and placebo in mean SKAMP-C score across the entire laboratory classroom trial.

Adolescents (12-17 years of age)

Very common treatment-emergent adverse events reported by ≥5% of adolescents with ADHD treated with FOQUEST® in a 6-month open-label clinical trial[2]

Headache	15.2% (27/178)
Insomnia	15.2% (27/178)
Decreased appetite	14.6% (26/178)

Adapted from FOQUEST® product monograph.

The incidence of abdominal pain in the 4-week double-blind trial was 1.0% (3/293).[2]

Most of the events were mild or moderate in severity.[2]

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FOQUEST® SAFETY PROFILE

Adults: Pivotal trial

Very common treatment-emergent adverse events reported by ≥1% of adults with ADHD treated with FOQUEST®[2]

Headache	17.5% (52/279)
Insomnia	22.6% (67/279)
Decreased appetite	11.1% (33/279)
Abdominal pain	1.3% (4/279)

Adapted from FOQUEST® product monograph.

Adults: Post-market trial

Very common treatment-emergent adverse events reported by ≥1% of adults with ADHD in a laboratory classroom study with an up to 7-week open-label titration phase, followed by a 1-week double-blind treatment phase[2]*

	Open-label phase (up to 7 weeks)	**Double-blind phase** (1 week)	
	FOQUEST®	**FOQUEST®**	**Placebo**
Headache	21.4% (61/285)	4.1% (5/121)	2.5% (3/118)
Insomnia	16.1% (46/285)	1.7% (2/121)	1.7% (2/118)
Decreased appetite	21.4% (61/285)	0.8% (1/121)	0
Abdominal pain	4.2% (12/285)	NR	NR

Adapted from FOQUEST® product monograph.
NR=not reported.
* Randomized, double-blind, multicentre, placebo-controlled trial involving 285 adult patients (18 to 60 years of age) who met the DSM-5 criteria for ADHD. Following an up to 7 week dose optimization period (FOQUEST® titrated from 25 mg to 100 mg), patients entered a one-week randomized, double-blind treatment with FOQUEST® (n=121; full analysis set) or placebo (n=118; full analysis set). At the end of this week, subjects completed an age-adjusted math test assessment in a laboratory classroom setting using the PERMP test. The primary efficacy endpoint was the difference between FOQUEST® and placebo in mean PERMP Total score across the entire laboratory classroom trial.

Most of the events were mild or moderate in severity.[2]

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SERIOUS ADVERSE EVENTS (AEs) AND AEs LEADING TO TREATMENT DISCONTINUATION

Children
(6-12 years of age)

During the open-label period (6 weeks):	**During the double-blind treatment phase of the placebo-controlled trial** (1 week):
• **1.3%** (2/156) of FOQUEST®-treated patients discontinued treatment due to AEs - 1 subject (0.6%) with affect lability and dermatillomania and 1 subject (0.6%) with ECG PR prolongation • **No SAEs were reported**	• **No discontinuations** due to AEs or serious adverse events (SAEs)

Adolescents
(12-17 years)

During the double-blind treatment phase of the placebo-controlled trial (4 weeks):	**During the 6-month open-label safety trial**:
• **3.4%** (10/293) of FOQUEST®-treated patients discontinued treatment due to AEs - AEs that led to discontinuation were: irritability (3 subjects [1.0%]), anxiety, delirium, depressed mood, dysphoria, suicidal ideation, dizziness, and headache (each one of 293 subjects, 0.3%) • **No SAEs were reported**	• **5.0%** (9/179) of subjects discontinued due to AEs – one subject each (0.6%) with asthma exacerbation, depressed mood, flat affect, generalized anxiety disorder, insomnia, decreased appetite, headache, urticaria chronic, and severe aggressive behaviour • **2 subjects experienced SAEs**, including asthma exacerbation and severe aggressive behaviour

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SAEs AND AEs LEADING TO TREATMENT DISCONTINUATION

Adults
(≥18 years)

Double-blind treatment phase of pivotal trial (4 weeks):	**6-month open-label safety trial**:	**Open-label treatment phase of post-market trial** (up to 7 weeks):
• **2.7%** (8/297) of FOQUEST® patients discontinued treatment due to AEs vs. 2.6% (2/78) who received placebo • AEs that led to discontinuation included: anxiety 0.7% (2/297); insomnia 0.7% (2/297); lip swelling 0.3% (1/297); affect lability 0.3% (1/297); emotional disorder 0.3% (1/297); and irritability 0.3% (1/297)	• **4.9%** (9/184) of FOQUEST® patients discontinued treatment due to AEs • AEs leading to discontinuation included: insomnia 1.1% (2/184); weight decreased 0.5% (1/184); balance disorder 0.5% (1/184), viith nerve paralysis 0.5% (1/184); anxiety 0.5% (1/184); depression 0.5% (1/184); irritability 0.5% (1/184); and nervousness 0.5% (1/184)	• **3.5%** (10/285) of FOQUEST® patients discontinued treatment due to AEs • 1 subject (0.4%) with decreased appetite, anxiety and insomnia, 1 subject (0.4%) with headache and flat affect, and 1 subject each with ST segment depressed (0.4%), jitteriness (0.4%), heart palpitations (0.4%), irritability (0.4%), anxiety (0.4%), nausea (0.4%), headache (0.4%)
• **1 SAE** occurred (uterine cancer)	• **4 SAEs** occurred: tendon rupture (n=1), breast cancer (n=1), dizziness (n=1) and viith nerve paralysis (n=1)	• **1 SAE** of acute paranoia (0.4%) occurred

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WANT TO LEARN MORE?

Ask your Health Solutions Consultant for additional clinical safety data to support your ADHD treatment decision making.

Clinical Use:
FOQUEST® is indicated as an integral part of a total treatment program for ADHD that may include other measures (i.e., psychological, educational and/or social) for patients with this syndrome. Drug treatment may not be indicated for all patients with this syndrome. Drug treatment is not intended for use in the patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Geriatrics: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use. FOQUEST® should not be used in children under 6 years of age. No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use in patients under 6 years of age. The effectiveness of FOQUEST® has not been evaluated for more than 4 weeks in placebo-controlled clinical trials. If electing to use FOQUEST® for extended periods, the long-term usefulness of the drug for the individual patient should be periodically re-evaluated.

Contraindications:
- Known hypersensitivity or idiosyncrasy to sympathomimetic amines
- Thyrotoxicosis
- Advanced arteriosclerosis
- Symptomatic cardiovascular disease
- Moderate to severe hypertension
- Glaucoma
- Patients with a history of drug abuse
- During or within 14-days following the administration of monoamine oxidase inhibitors (hypertensive crises may result)

Most Serious Warning and Precaution:
Drug dependence. Like other stimulants, FOQUEST® has the potential to be abused, leading to dependence and tolerance.

Other Relevant Warnings and Precautions:
- The safety of methylphenidate has been studied in a 6-month open-label trial. Long-term effects of methylphenidate have not been well established beyond 6 months in adolescents (12-17 years of age) and 7 weeks in children (6-11 years of age)
- Caution in patients who: are involved in strenuous exercise or activities, use other stimulants, or have a family history of sudden/cardiac death
- Sudden death, stroke, and myocardial infarction
- CNS stimulants should be used with caution in patients with a condition of the cardiovascular or cerebrovascular system
- Hypertension
- Misuse may cause serious cardiovascular adverse events and sudden death
- Alcohol should not be taken with FOQUEST®
- Long-term suppression of growth: Carefully monitor patients requiring long-term therapy. Interrupt treatment in patients not growing or gaining weight as expected
- Increase in seizure frequency
- Onset or exacerbation of motor and verbal tics
- Impairment in ability to operate machinery or vehicles
- Visual disturbances
- Psychiatric effects: Not for treatment of depression; not for use in treatment or prevention of normal fatigue states; may exacerbate psychosis symptoms in patients with pre-existing psychotic disorder; screen for risk of bipolar disorder in patients with comorbid depressive symptoms; monitor patients for signs of suicide-related behaviour; monitor patients for new psychotic or manic episodes, aggressive behaviour, marked anxiety, or agitation
- Serotonin syndrome has been reported with methylphenidate, including FOQUEST®, with concomitant use of serotonergic or dopaminergic drugs; if concomitant treatment with FOQUEST® and other serotonergic agents is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases
- Priapism
- Peripheral vasculopathy, including Raynaud's phenomenon
- Not to be given to pregnant women unless the potential benefit outweighs the risk to the fetus
- Either abstain from breastfeeding or abstain from FOQUEST® therapy, taking into account the benefit of breastfeeding to the child and the benefit of therapy to the woman
- Periodic laboratory tests are advised during prolonged therapy
- FOQUEST® has the potential for misuse and dependence

For More Information:
Please consult the product monograph at https://elvium.ca/wp-content/uploads/FOQUEST-PM-EN.pdf for important information relating to adverse reactions, drug interactions (particularly with co-administration of clonidine), and dosing information which have not been discussed in this piece. The product monograph is also available by calling us at 1-833-744-0005.

References: 1. CADDRA - Canadian ADHD Resource Alliance: Canadian ADHD Practice Guidelines, 4.1 Edition, Toronto ON; CADDRA, 2020. **2.** <C>FOQUEST® Product Monograph. Elvium Life Sciences. August 28, 2023.

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REVIEWED BY PAAB

INNOVATIVE MEDICINES CANADA

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