ELVIUM'S METHYLPHENIDATE HCl PORTFOLIO

Uniquely engineered with multi-layer release (MLR) bead technology[1-3*†]

FOQUEST®

1. Immediate-release layer: **20% methylphenidate HCl**
2. Delayed-release coating
3. Controlled-release coating
4. Controlled-release layer: **80% methylphenidate HCl**
5. Sugar sphere

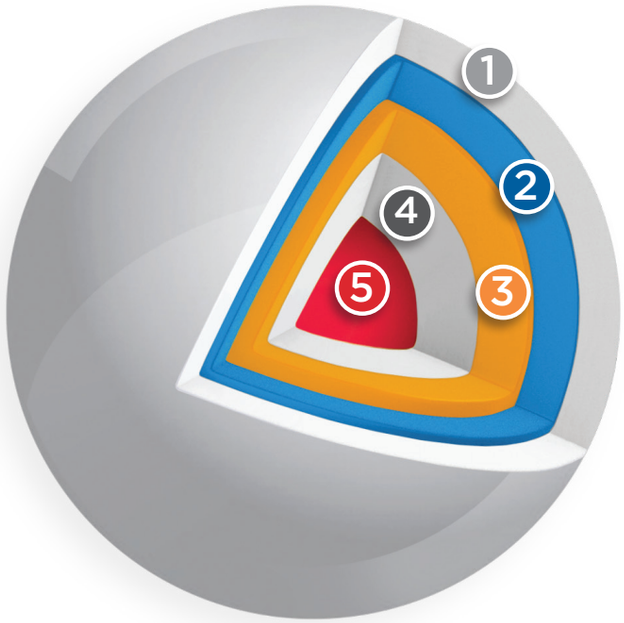
20% of the total dose is contained in an IR layer
80% (the remainder of the total dose) is in the delayed release layers[1*]

- **Designed to provide a biphasic release of methylphenidate, from an immediate-release layer of the drug and delayed controlled release layers of the drug[1*]**

FOQUEST® (methylphenidate hydrochloride controlled release capsules) is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥6 years of age.[1]

* Clinical significance is unknown.

Biphentin®



1. Immediate-release layer: **40% methylphenidate HCl**
2. Delayed-release coating
3. Controlled-release coating
4. Controlled-release layer: **60% methylphenidate HCl**
5. Sugar sphere

Adapted from Reiz JL, *et al*.[2*]

40% of the total dose is contained in an IR layer
60% (the remainder of the total dose) is in the delayed CR layers

- **Designed to be an alternative to separate doses of immediate-release methylphenidate by providing a biphasic plasma concentration-time profile when given as a single dose[3*]**

BIPHENTIN® (methylphenidate hydrochloride controlled release capsules) is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6-11, adolescents 12-18, and adults >18 years of age.[3]

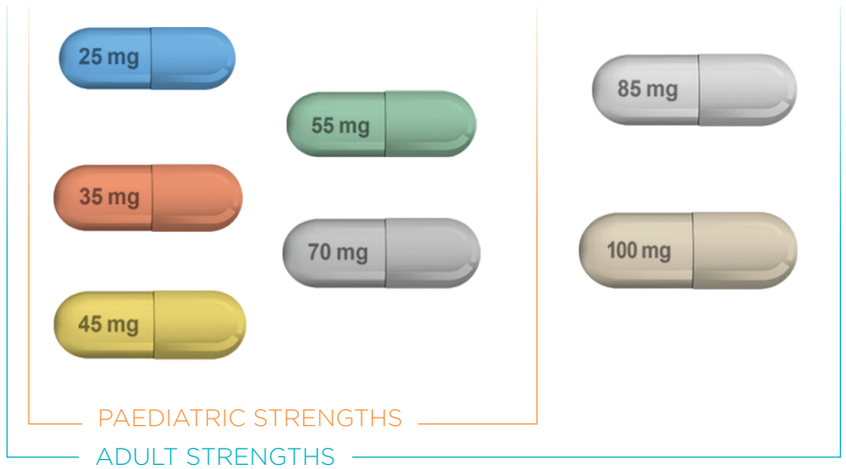
* Clinical significance is unknown.
† Comparative clinical significance is unknown.

FLEXIBLE DOSING AND ADMINISTRATION

Wide range of strengths to assist with titration[1,3]

FOQUEST®

FOQUEST® Vegetarian Capsules



- Maximum daily dose for children and adolescents (6 to <18 years): 70 mg
- Maximum daily dose for adults (≥18 years old): 100 mg

Please see product monograph for complete dosing and administration instructions.

FOQUEST® should be administered starting at the lowest possible dose. Dosage should then be individually and slowly adjusted to the lowest effective dosage since individual patient response to FOQUEST® varies widely.

The effect of FOQUEST® might last into the evening; take as soon as possible in the morning to avoid any potential effect on sleep.

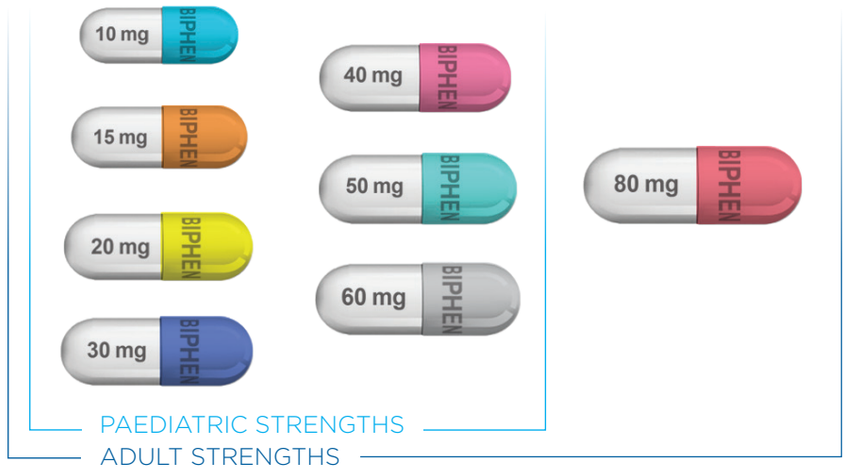
FOQUEST® should not be used in patients with symptomatic cardiovascular disease and should generally not be used in patients with known structural cardiac abnormalities.

Patients who are considered to need extended treatment with FOQUEST® should undergo periodic evaluation of their cardiovascular status.

Do not substitute for immediate release methylphenidate tablets or other controlled release methylphenidate products on a milligram for milligram basis because of differing pharmacokinetic profiles.

Biphentin®

Biphentin® Gelatin Capsules



- Maximum daily dose in children ≥6 years: 60 mg
- Maximum daily dose in adults >18 years old to <65 years old: 80 mg

Please see product monograph for complete dosing and administration instructions.

BIPHENTIN® has not been compared to other controlled release methylphenidate preparations on the Canadian market and therefore is not interchangeable.

BIPHENTIN® should be administered starting at the lowest possible dose. Dosage should then be individually and slowly adjusted to the lowest effective dosage since individual patient response to BIPHENTIN® varies widely.

If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or if necessary, discontinue the drug.

BIPHENTIN® should be periodically discontinued to assess the patient's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Patients currently receiving immediate release formulations of methylphenidate may be converted to the next lower strength, based on the total methylphenidate daily dose. Dosage should then be individually and slowly adjusted, to the lowest effective dosage. The maximum daily dose should not exceed 60 mg for children and adolescents (6–18 years) or 80 mg for adults (>18 years).

BIPHENTIN® should not be used in patients with symptomatic cardiovascular disease and should generally not be used in patients with known structural cardiac abnormalities. All drugs with sympathomimetic effects prescribed in the management of ADHD should be used with caution in patients who: a) are involved in strenuous exercise or activities, b) use other stimulants, or c) have a family history of sudden/cardiac death. Prior to initiating treatment, a personal and family history (including assessment for a family history sudden death or ventricular arrhythmia) and physical exam should be obtained to assess for the presence of cardiac disease. In patients with relevant risk factors and based on the clinician's judgement, further cardiovascular evaluation may be considered (e.g., electrocardiogram and echocardiogram).

FOQUEST® and BIPHENTIN®: ADMINISTRATION OPTIONS

Both FOQUEST® and BIPHENTIN® capsules can be **swallowed whole** or **sprinkled, but never crushed or chewed.**

Once daily in the morning[1,3]

SPRINKLE OPTION[1,3]

1. Open the capsule
2. Sprinkle entire contents onto a tablespoon of:
   - Applesauce
   - Ice Cream
   - Yogurt

AFTER SPRINKLING FOQUEST®...

- Consume entire mixture immediately, or within 10 minutes, without chewing.
- Do not sprinkle in liquids.
- Rinse mouth with water afterwards to ensure that the entire contents are swallowed.

FOQUEST®

Biphentin®

FOQUEST®

Guideline-recommended **first-line** for the treatment of children, adolescents and adults with ADHD[4,5]

FOQUEST® controlled release methylphenidate hydrochloride capsules
Once Daily

Clinical Use:
FOQUEST® is indicated as an integral part of a total treatment program for ADHD that may include other measures (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 for important information relating to adverse reactions, drug iinteractions (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.

BIPHENTIN® controlled release methylphenidate hydrochloride capsules
Once Daily

Clinical Use:

Effectiveness for more than 4 weeks has not been systematically evaluated in placebo-controlled trials. Physicians electing to use BIPHENTIN® for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient. BIPHENTIN® should not be used in children under 6 years of age. No data are available for patients >65 years of age; therefore, Health Canada has not authorized an indication for geriatric use. BIPHENTIN® is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, and social) for patients with this syndrome. Drug treatment may not be indicated for all patients with this syndrome.

Contraindications:

- Anxiety, tension
- Agitation
- Thyrotoxicosis
- Advanced arteriosclerosis
- Symptomatic cardiovascular disease
- Moderate to severe hypertension
- Glaucoma
- History of drug abuse
- Motor tics or with family history or diagnosis of Tourette's syndrome
- Concomitant use of an MAO inhibitor, or within a minimum of 14 days following discontinuation of an MAO inhibitor

Most Serious Warning and Precaution:

Drug dependence/tolerance. Should be given cautiously particularly to those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative. Chronic abuse can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of an underlying disorder that may require follow-up.

Other Relevant Warnings and Precautions:

- Non-interchangeability with other controlled release methylphenidate preparations
- The misuse of central nervous system (CNS) stimulants may cause serious cardiovascular adverse events and sudden death
- The risk of sudden cardiac death should be considered, although incremental risk of adverse cardiac events has not been confirmed
- Patients who are involved in strenuous exercise or activities; are using other stimulants or medications for ADHD; or have a family history of sudden cardiac death
- Cardiovascular: sudden death and pre-existing structural cardiac abnormalities or other serious heart problems
- Screen for cardiovascular and cerebral vascular conditions before initiating treatment and monitor for new conditions during treatment
- Monitor blood pressure at appropriate intervals especially in patients with pre-existing conditions that may result in hypertension
- Long-term suppression of growth: Carefully monitor patients requiring long-term therapy. Interrupt treatment in patients not growing or gaining weight as expected
- Should not be used in the treatment of severe exogenous or endogenous depression
- Should not be used in treatment or prevention of normal fatigue states
- Pre-existing psychosis: May exacerbate symptoms of behavioural disturbance and thought disorder
- Bipolar disorder: Screen patients with comorbid depressive symptoms
- Emergence of new psychotic or manic symptoms
- Aggression, anxiety and agitation
- Suicidal behaviour and ideation: Monitor for signs at dose initiation, optimization and discontinuation
- Serotonin syndrome
- Neurologic effects: Discontinue if seizure frequency rises
- Onset or exacerbation of motor and verbal tics
- Ophthalmologic effects
- Priapism: Patients who develop abnormally sustained erections or frequent and painful erections should seek immediate medical attention
- Peripheral vasculopathy, including Raynaud's phenomenon; observe for digital changes
- Not for use in pregnant women unless the potential benefit outweighs the risk to the fetus. A risk to the suckling child cannot be excluded
- Patients with an element of agitation may react adversely; discontinue therapy if necessary
- Due caution should be exercised when driving or operating machinery
- Monitoring and laboratory tests are recommended during prolonged therapy

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Elvium Life Sciences
Toronto, ON
M2H 3S7

CA-FOQ-2300084E

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- **Designed to provide a biphasic release of methylphenidate, from an immediate-release layer of the drug and delayed controlled release layers of the drug[1*]**

FOQUEST® (methylphenidate hydrochloride controlled release capsules) is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ≥6 years of age.[1]

* Clinical significance is unknown.

Biphentin®

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† Comparative clinical significance is unknown.

Guideline-recommended **first-line** for the treatment of children, adolescents and adults with ADHD[4,5]

FOQUEST® controlled release methylphenidate hydrochloride capsules Once Daily

Clinical Use:
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- 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
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- 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
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- The risk of sudden cardiac death should be considered, although incremental risk of adverse cardiac events has not been confirmed
- Patients who are involved in strenuous exercise or activities; are using other stimulants or medications for ADHD; or have a family history of sudden cardiac death
- Cardiovascular: Sudden death and pre-existing structural cardiac abnormalities or other serious heart problems
- Screen for cardiovascular and cerebral vascular conditions before initiating treatment and monitor for new conditions during treatment
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Toronto, ON
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CA-FOQ-2300084E

FOQUEST®
METHYLPHENIDATE HYDROCHLORIDE CONTROLLED RELEASE CAPSULES

Please see product monograph for complete dosing and administration instructions.

FOQUEST® should be administered starting at the lowest possible dose. Dosage should then be individually and slowly adjusted to the lowest effective dosage since individual patient response to FOQUEST® varies widely.

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Patients who are considered to need extended treatment with FOQUEST® should undergo periodic evaluation of their cardiovascular status.

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Biphentin®
Controlled release methylphenidate hydrochloride capsules

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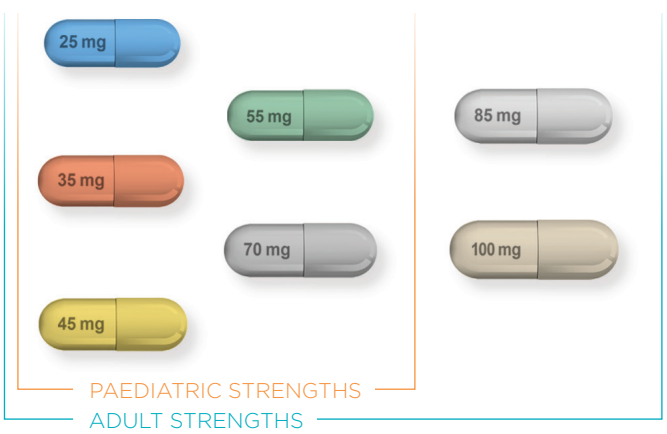
FLEXIBLE DOSING AND ADMINISTRATION

Wide range of strengths to assist with titration[1,3]

FOQUEST®

Biphentin®

FOQUEST® Vegetarian Capsules



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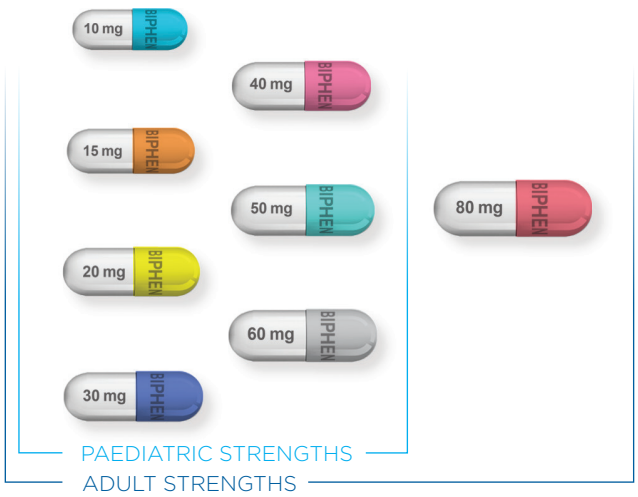
Biphentin® Gelatin Capsules



- Maximum daily dose in children >6 years: 60 mg
- Maximum daily dose in adults >18 years old to <65 years old: 80 mg

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Once daily in the morning[1,3]

SPRINKLE OPTION[1,3]

1. Open the capsule
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   - Applesauce
   - Ice Cream
   - Yogurt

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- Consume entire mixture immediately, or within 10 minutes, without chewing.
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- Rinse mouth with water afterwards to ensure that the entire contents are swallowed.