

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE



#### Methylphenidate hydrochloride controlled release Capsules

Read this carefully before you or your child start taking **FOQUEST®** and each time you or your child get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to you or your child's healthcare professional about your medical condition and treatment and ask if there is any new information about **FOQUEST**.

#### Serious Warnings and Precautions

- **Drug Dependence**

**Like other stimulants, FOQUEST has the potential to be abused. This can lead you to becoming dependant on FOQUEST or feeling like you need to take more of it over time. Abuse of FOQUEST can lead to dependence.**

#### What is FOQUEST used for?

- FOQUEST is a once-daily treatment for Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

#### FOQUEST is **NOT** recommended for use in children under 6 years of age.

Treatment with FOQUEST, or other stimulants, should be combined with other measures, such as psychological counselling, educational and social measures, as part of a total treatment program.

#### How does FOQUEST work?

FOQUEST contains methylphenidate hydrochloride, which belongs to a group of medicines called central nervous system stimulants. It works by changing the levels of certain chemicals in the brain. This helps to increase attention and decrease impulsivity and hyperactivity in patients with ADHD.

#### What are the ingredients in FOQUEST?

Medicinal ingredients: methylphenidate hydrochloride

Non-medicinal ingredients: ammonio methacrylate copolymer dispersion (type B), anionic copolymer (consisting of methyl acrylate, methyl methacrylate and methacrylic acid), glyceryl monostearate, hypromellose, poylethylene glycol, polysorbate, silicon dioxide, sodium hydroxide, sodium lauryl sulfate, sorbic acid, sugar spheres, and triethyl citrate

In addition, the capsule shells contain the following non-medicinal ingredients:

- 25 mg: FD&C Blue No. 1
- 35 mg: FD&C Yellow No. 6, Titanium Dioxide
- 45 mg: FD&C Yellow No. 5, Titanium Dioxide
- 55 mg: FD&C Blue No. 1, Titanium Dioxide, Yellow Iron Oxide
- 70 mg: Black Iron Oxide, Titanium Dioxide
- 85 mg: Titanium Dioxide
- 100 mg: Red Iron Oxide, Titanium Dioxide, Yellow Iron Oxide

#### FOQUEST comes in the following dosage forms:

Controlled release capsules: 25 mg (blue), 35 mg (orange), 45 mg (yellow), 55 mg (light green), 70 mg (iron gray), 85 mg (white), 100 mg (cream)

**Do not use FOQUEST if you or your child:**

- are allergic to methylphenidate hydrochloride, any other central nervous system stimulants, or any of the other ingredients in FOQUEST.
- have ever had heart problems such as a heart attack, irregular heartbeat, chest pain, heart failure, heart disease or were born with a heart problem.
- have glaucoma (increased eye pressure).
- have moderate to severe high blood pressure.
- have hardened arteries.
- have an overactive thyroid gland.
- are taking or have taken within the past 14-days medications from a group called monoamine oxidase (MAO) inhibitors.
- have a history of drug abuse.

**To help avoid side effects and ensure proper use, talk to your or your child's healthcare professional before you take FOQUEST. Talk about any health conditions or problems you may have, including if you or your child:**

- have mild high blood pressure, heart problems or heart defects.
- have a family history of sudden cardiac death.
- have thyroid problems.
- have had seizures or abnormal EEGs (measure of brainwave activity).
- do high-intensity exercise or activities.
- have mental health problems or family history of mental health problems, including:
  - anxiety
  - psychosis
  - mania
  - bipolar disorder
  - depression
  - aggression
  - suicide
- drink alcohol or have a history of alcohol abuse. You or your child should not drink alcohol while taking FOQUEST.
- have circulation problems in fingers and toes, including numbness, feeling cold or pain (this is also known as Raynaud's phenomenon).
- are pregnant or plan to become pregnant. FOQUEST should not be used during pregnancy.
- are breastfeeding or plan to breastfeed. FOQUEST can pass through breast milk. You should consult with your or your child's healthcare professional to determine whether to stop breast-feeding or discontinue FOQUEST.
- take other drugs for ADHD or depression.
- have tics (movements or sounds that you cannot control) or Tourette's syndrome, or if someone in your family has tics or Tourette's syndrome.

**Other warnings you should know about:**

**Driving and Using Machines:** FOQUEST can affect the ability to drive and use potentially dangerous tools or machinery. You or your child should not drive or use tools or machinery until you know how you or your child respond to FOQUEST.

**Dependence and Tolerance:** Like other stimulants, FOQUEST has the potential to be abused if not taken correctly which can lead to dependence and tolerance. If you or your child have a history of

drug or alcohol abuse, discuss this with your or your child's healthcare professional. Do not change the dose or stop taking FOQUEST without first discussing this with your or your child's healthcare professional. If you stop taking FOQUEST, you will need careful supervision because you may feel very depressed.

**Growth in children:** Slower growth (weight gain and/or height) has been reported with long-term use of methylphenidate hydrochloride in children. Your healthcare professional will carefully watch your child's height and weight. If your child is not growing or gaining weight as expected, your healthcare professional may stop treatment.

**Heart Related Problems:** The following heart related problems have been reported in people taking medicine to treat ADHD like FOQUEST:

- Sudden death in patients who have heart problems or heart defects
- Stroke and heart attack
- Increased blood pressure
- Increased heart rate

Sudden death has been reported in association with stimulant drugs for ADHD treatment in children with structural heart abnormalities. FOQUEST generally should not be used in children, adolescents or adults with known structural heart abnormalities.

Tell your healthcare professional if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your healthcare professional will check:

- you for heart problems before starting FOQUEST
- your blood pressure and heart rate regularly during treatment with FOQUEST

**Seek immediate medical help if you or your child have any signs of heart problems such as chest pain, difficulty breathing or fainting while taking FOQUEST.**

**Mental Health Problems:** The following mental health problems have been reported in people taking medicine to treat ADHD like FOQUEST:

- New or worse thoughts or feelings of suicide (thinking about or feeling like killing yourself) and suicide attempt
- New or worse bipolar disorder (extreme mood swings, with periods of excitement, switching between periods of sadness)
- New or worse aggressive behavior or hostility
- New psychotic symptoms (such as hearing voices, believing things that are not true, being suspicious)

These new or worse mental health problems may be more likely to occur if you or your child have mental health conditions that you may or may not know about. Tell your healthcare professional about any mental problems or about any personal or family history of suicide, bipolar illness, or depression you or your child have.

A small number of patients taking ADHD drugs may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time during treatment, particularly at the start or during dose changes, and also after stopping FOQUEST. **Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your healthcare professional immediately. Close observation by a healthcare professional is necessary in this situation.**

**Serotonin toxicity (also known as Serotonin Syndrome):** Serotonin toxicity is a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive

system work. You may develop serotonin toxicity if you take FOQUEST with certain anti-depressants or migraine medications. Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

**Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

#### **Serious Drug Interactions**

**Do not take FOQUEST if you:**

- are taking or have recently taken (in the last 14 days) any monoamine oxidase inhibitor (MAOIs) as you may have serious side effects.

**Taking FOQUEST and clonidine (used to treat high blood pressure) may cause serious side effects or sudden death.**

**The following may interact with FOQUEST:**

- Alcohol should be avoided, including any medications containing alcohol, such as some cough syrups, while taking FOQUEST
- Certain medicines used to treat or prevent blood clot, such as warfarin
- Certain medicines used to treat seizures, such as phenobarbital, phenytoin, or primidone
- Certain medicines for depression and mood disorders, such as Tricyclic Antidepressants (e.g. amitriptyline) and Selective Serotonin Reuptake Inhibitors (SSRIs).
- Certain medicines used to treat high blood pressure
- Medicines used to manage psychosis (antipsychotics)

**How to take FOQUEST:**

- Your or your child's healthcare professional will decide the dose that is right. Always follow the directions of the healthcare professional and never change the dose or stop taking FOQUEST without first discussing it with your or your child's healthcare professional.
- FOQUEST should be taken once-a-day, with or without food, as soon as possible in the morning as the effects of FOQUEST can last late into the evening and may affect sleep.
- **FOQUEST capsules should be swallowed whole with a full glass of water and must never be crushed or chewed.**
- For patients unable to swallow the capsule, the capsule may be opened and the entire contents sprinkled onto applesauce, ice cream or yogurt. Do not sprinkle in liquids.

- **To sprinkle FOQUEST onto food:**
  1. Measure a tablespoon of applesauce, ice cream or yogurt.
  2. Open the capsule.
  3. Sprinkle the entire contents (beads) onto the tablespoon.
  4. Take the entire mixture **immediately or within 10 minutes**.
    - Do **not** chew the capsule contents (beads).
    - Rinse your or your child's mouth with water and swallow the water.
    - Do **not** keep any of the food/medicine mixture for another dose.
    - Throw out any food/medicine mixture if:
      - it has been more than 10 minutes since you sprinkled the capsule onto the food.
      - you do not remember when you sprinkled the capsule onto the food.
      - you do not remember which food you sprinkled the capsule onto.

#### **Usual dose:**

- Take the dose prescribed by your or your child's healthcare professional.
- The starting dose will depend on whether you or your child have already been taking a medication that contains methylphenidate (the ingredient in FOQUEST).
- The healthcare professional may adjust the amount of medicine until it is right for you or your child.
- From time to time, the healthcare professional may interrupt treatment with FOQUEST to check for symptoms while you or your child are not taking the medicine.
- The maximum daily dose for children and adolescents (6 to <18 years old) is 70 mg.
- The maximum daily dose for adults (≥18 years old) is 100 mg.

#### **Overdose:**

If you think you, your child, or a person you are caring for, have taken too much FOQUEST, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

#### **Missed Dose:**

If you or your child forget to take the dose in the morning, wait until the next day and take the usual dose at the usual time in the morning. Do not take an afternoon dose. Do not double the dose to make up for the missed dose.

#### **What are possible side effects from using FOQUEST?**

These are not all the possible side effects you or your child may have when taking FOQUEST. If you experience any side effects not listed here, tell your or your child's healthcare professional.

Side effects may include:

- Loss of appetite
- Headache
- Insomnia, sleep disorder

- Abdominal pain and discomfort
- Dry mouth
- Diarrhea, nausea, vomiting
- Fatigue, drowsiness
- Feeling jittery, nervousness or anxiety
- Weight loss, weight gain
- Sinus infection, common cold
- Heart rate increase
- Dizziness
- Irritability
- Increased sweating
- Difficulty opening the mouth (trismus)
- Inability to control excretion of urine (incontinence)
- Swelling of the breasts in boys or men

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
<b>Mental Health Problems:</b> <ul style="list-style-type: none"><li>• Paranoia, delusions</li><li>• Hallucinations: seeing, feeling or hearing things that are not real</li><li>• Mania: feeling unusually excited, or over-active</li><li>• Depression</li><li>• Agitation, irritability, anxiety, nervousness</li><li>• Aggression, hostility</li><li>• Compulsions</li></ul>		✓	
COMMON			
<b>Heart Problems:</b> fast heartbeat, palpitations, chest pain, difficulty breathing, fainting			✓
<b>Eye Problems:</b> blurred vision, abnormal blinking or eyelid spasms		✓	
<b>Hypertension</b> (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or fast or uneven heartbeat.	✓		
UNKNOWN			
<b>Suicidal Behaviour:</b> thoughts or feelings about harming yourself			✓
<b>Raynaud’s Phenomenon:</b> discoloration of the fingers and toes, pain, sensations of cold and/or numbness		✓	
<b>Seizures or Convulsions:</b> loss of consciousness with uncontrollable shaking (fit)			✓
<b>Serious Allergic Reaction:</b> itching, skin rash, swelling of the mouth, face, lips, or tongue, trouble swallowing, trouble breathing			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Priapism:</b> long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
<b>Rhabdomyolysis</b> (breakdown of damaged muscle): muscle weakness, muscle pain, muscle spasms, red-brown coloured urine		✓	
<b>Bladder Infection:</b> increased need to urinate, pain when urinating, blood in the urine		✓	
<b>Tourette's Syndrome:</b> motor tics (hard-to-control, repeated twitching of any part of your body) and verbal tics (hard-to-control repeating of sounds or words)			✓
<b>Edema:</b> swollen hands, ankles or feet	✓		
<b>Nosebleed</b>	✓		

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your or your child's healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

**Keep unused or expired FOQUEST in a secure place to prevent theft, misuse or accidental exposure. Keep FOQUEST out of sight and reach of children and pets.**

Store at room temperature (15°C to 30°C). Protect from moisture.

**FOQUEST should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.**

### If you want more information about FOQUEST:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.elvium.ca](http://www.elvium.ca), or by calling 1-833-744-0005

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