

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

◆ **FOQUEST®**
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 your or your child's healthcare professional about the medical condition and treatment and ask if there is any new information about **FOQUEST**.

Serious Warnings and Precautions

Drug Dependence

Abuse of **FOQUEST** can lead to dependence. Tell your or your child's healthcare professional if you or your child have ever abused or been dependent on alcohol or drugs, or are now abusing or dependent on alcohol or drugs.

What is FOQUEST used for?

FOQUEST is used to treat Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older.

FOQUEST is one part of your or your child's treatment program. Your or your child's healthcare professional can help you find the counselling and support that is needed for a complete 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 is Attention Deficit Hyperactivity Disorder (ADHD)?

Patients with ADHD have problems with attention, hyperactivity and impulse control. These symptoms interfere with the patient's daily life. Some patients have symptoms related to hyperactivity and impulse control while others have symptoms related to inattention. Some patients have both types of symptoms. Many people have symptoms like these from time to time, but patients with ADHD have these symptoms more than others their age.

Symptoms of inattention include:

- Not paying attention
- Making careless mistakes
- Not listening

- Not finishing tasks
- Not following directions
- Having difficulty with organization
- Avoiding or disliking tasks that require a lot of thinking
- Losing things
- Being forgetful
- Being easily distracted

Symptoms of hyperactivity and impulsivity include:

- Fidgeting
- Having difficulty remaining seated
- Feeling restlessness
- Having difficulty with quiet activities
- Often being “on the go”
- Talking excessively
- Having difficulty waiting or taking turns
- Interrupting others

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, polyethylene glycol, polysorbate, silicon dioxide, sodium hydroxide, sodium lauryl sulfate, sorbic acid, sugar spheres, triethyl citrate

Strength (mg)	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, Yellow Iron Oxide, Titanium Dioxide
70 mg	Black Iron Oxide, Titanium Dioxide
85 mg	Titanium Dioxide
100 mg	Yellow Iron Oxide, Red Iron Oxide, Titanium Dioxide

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 taking FOQUEST. Talk about any health conditions or problems you or your child 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.

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**

Your or your child's healthcare professional will check carefully for heart problems before starting **FOQUEST** and will check 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 happen if you or your child have mental health conditions. These symptoms can happen at any time during treatment but are more likely to occur when you or your child first start taking **FOQUEST**, when the dose changes, or after stopping **FOQUEST** treatment.

A small number of patients taking ADHD drugs may have feelings of:

- agitation
- hostility
- anxiety, or
- have thoughts of suicide, self-harm or harm to others.

Seek immediate medical help if you or your child have any mental health symptoms while taking FOQUEST.

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

The following may interact with FOQUEST:

- Alcohol should be avoided, including any medications containing alcohol, such as some cough syrups, while taking **FOQUEST**
- Clonidine used to treat ADHD
- 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). Do not take **FOQUEST** with monoamine oxidase (MAO) inhibitors or if you or your child have taken MAO inhibitors in the last 14-days before treatment with **FOQUEST**.
- Certain medicines used to treat high blood pressure

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 or your child have taken too much **FOQUEST**, contact your or your child's 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 that you or your child may feel when taking **FOQUEST**. If you or your child experience any side effects not listed here, contact 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
- Weight loss, weight gain
- Sinus infection, common cold
- Heart rate increase
- Dizziness
- Irritability

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			
Mental Health Problems: <ul style="list-style-type: none"> • Paranoia, delusions • Hallucinations: seeing, feeling or hearing things that are not real • Mania: feeling unusually excited, or over-active • Depression • Agitation, irritability, anxiety, nervousness • Aggression, hostility • Compulsions 		✓	
Common			
Heart Problems: fast heartbeat, palpitations, chest pain, difficulty breathing, fainting			✓
Eye Problems: blurred vision, abnormal blinking or eyelid spasms		✓	
Unknown			
Suicidal Behaviour: thoughts or feelings about harming yourself			✓
Raynaud’s Phenomenon: discoloration of the fingers and toes, pain, sensations of cold and/or numbness		✓	
Seizures or Convulsions: loss of consciousness with uncontrollable shaking (fit)			✓
Serious Allergic Reaction: itching, skin rash, swelling of the mouth, face, lips, or tongue, trouble swallowing, trouble breathing			✓
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
Bladder Infection: increased need to urinate, pain when urinating, blood in the urine		✓	
Tourette’s Syndrome: motor tics (hard-to-control, repeated twitching of any part of your body) and verbal tics (hard-to-control repeating of sounds or words)			✓
Edema: swollen hands, ankles or feet	✓		

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

Disposal:

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 or your child's 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.elvium.ca, or by calling 1-833-744-0005

This leaflet was prepared by Elvium Life Sciences.

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