

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

 **BIPHENTIN®**

Methylphenidate hydrochloride controlled-release capsules

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

Serious Warnings and Precautions

- **Drug Dependence**
Like other stimulants, **BIPHENTIN** has the potential to be abused. This can lead to you becoming dependent on **BIPHENTIN** or cause you to need a higher dose to have the same effect.

What is **BIPHENTIN** used for?

- **BIPHENTIN** is a once-daily treatment for Attention-Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents and adults.

BIPHENTIN is NOT recommended for use in children under 6 years of age.

Treatment with **BIPHENTIN**, 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 **BIPHENTIN** work?

BIPHENTIN belongs to a group of medicines called central nervous system stimulants. The way **BIPHENTIN** works in the brain is not completely known. **BIPHENTIN** helps increase attention and decrease impulsiveness and hyperactivity in patients with ADHD. It is designed to be taken as a single dose in the morning to help symptoms of ADHD by delivering the active ingredient, methylphenidate hydrochloride, to the bloodstream, both in the early morning, and later in the day.

What are the ingredients in **BIPHENTIN**?

Medicinal ingredients: methylphenidate hydrochloride.

Non-medicinal ingredients: ammonio methacrylate copolymer, type B; gelatin, hydroxypropyl methylcellulose, methacrylic acid and ethyl acrylate copolymer, polyethylene glycol, sugar spheres, talc, titanium dioxide and triethyl citrate.

In addition, the capsule shells also contain the following:

- 10 mg: FD&C Blue No. 1
- 15 mg: D&C Red No.28, D&C Yellow No. 10, FD&C Red No. 40
- 20 mg: D&C Red No. 33, D&C Yellow No. 10
- 30 mg: FD&C Blue No. 1, FD&C Red No. 3
- 40 mg: D&C Red No. 28, FD&C Blue No. 1, FD&C Red No. 40
- 50 mg: D&C Yellow No. 10, FD&C Green No. 3
- 60 mg: Black iron oxide
- 80 mg: FD&C Red No. 40, FD&C Yellow No. 6, D&C Yellow No. 10

BIPHENTIN comes in the following dosage forms:

Controlled-release capsules: 10 mg (light turquoise blue), 15 mg (orange), 20 mg (yellow), 30 mg (blue violet), 40 mg (pink), 50 mg (light green), 60 mg (iron grey) and 80 mg (reddish orange).

Do not use BIPHENTIN if:

- you are allergic to methylphenidate hydrochloride, any other central nervous system stimulants, or any of the other ingredients in BIPHENTIN
- you 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.
- you have anxiety, tension, or agitation.
- you have glaucoma (increased eye pressure).
- you have, or there is a family history of, motor tics (hard-to-control, repeated twitching of any parts of your body), verbal tics (hard-to-control repeating of sounds or words) or Tourette's syndrome.
- you have moderate to severe high blood pressure.
- you have hardened arteries.
- you have an overactive thyroid gland.
- you are taking or have recently taken (in the last 14 days) any medications from a group called monoamine oxidase inhibitors. This includes phenelzine, tranylcypromine, moclobemide.
- have a history of drug abuse.

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

- have mild high blood pressure, heart problems or heart defects, such as a serious structural heart abnormality.
- 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 a family history of mental health problems, including:
 - psychosis
 - mania
 - bipolar disorder
 - depression
 - aggression
 - suicide
- drink alcohol or have a history of alcohol abuse. You should not drink alcohol while taking BIPHENTIN.
- have circulation problems in fingers and toes, including numbness, feeling cold or pain (Raynaud's phenomenon).
- are pregnant or plan to become pregnant. BIPHENTIN should not be used during pregnancy.
- are breast-feeding or plan to breast-feed. BIPHENTIN can pass through your breast milk. You should consult with your healthcare professional to determine if you should stop breast-feeding or discontinue BIPHENTIN.
- take other drugs for ADHD or depression.

Other warnings you should know about:

Driving and using machines

BIPHENTIN can affect your ability to drive and use potentially dangerous tools or machinery. You should not drive or use tools or machinery until you know how you respond to BIPHENTIN.

Dependence and tolerance

Like other stimulants, BIPHENTIN has the potential to be abused, leading to dependence and tolerance. If you have a history of drug or alcohol abuse, talk to your healthcare professional. Do not change your dose or stop taking BIPHENTIN without first talking to your healthcare professional. If you stop taking BIPHENTIN, 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 BIPHENTIN:

- sudden death in patients who have heart problems or heart defects, such as structural heart abnormalities.
- 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. Since some serious heart problems alone can carry an increased risk of sudden death, BIPHENTIN generally should not be used in children, adolescents or adults with known serious structural heart abnormalities.

Tell your doctor if you/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 BIPHENTIN.
- your blood pressure and heart rate regularly during treatment with BIPHENTIN.

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

Mental health problems

The following mental health problems have been reported in people taking medicine to treat ADHD like BIPHENTIN:

- new or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide actions (suicide attempt, suicide ideation, suicide completed)
- 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/your child have mental

health conditions that you may or may not know about. Tell your doctor about any mental problems your or your child have, or about any personal or family history of suicide, bipolar illness, or depression.

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 BIPHENTIN. Should this happen to you, or to those in your care if you are a caregiver or guardian, consult your doctor immediately. Close observation by a doctor is necessary in this situation.

Seek immediate medical help if you have any mental health symptoms while taking BIPHENTIN.

Serotonin Syndrome

Serotonin syndrome 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 Syndrome if you take BIPHENTIN with certain antidepressants or migraine medications.

Serotonin syndrome 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 take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BIPHENTIN:

Serious Drug Interactions

Do not take BIPHENTIN if you are:

- taking or have recently taken (in the last 14 days) any MAOIs as you may have serious side effects.
- **Taking BIPHENTIN and Clonidine (used to treat high blood pressure) may cause serious side effects or sudden death.**

- alcohol – you/your child should avoid alcohol, including any medications containing alcohol, such as some cough syrups, while taking BIPHENTIN.
- certain medicines used to treat or prevent blood clots, 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 and Selective Serotonin Reuptake Inhibitors (SSRIs).
- certain medicines used to treat migraines.
- certain medicines used to treat nausea.
- medicines used to treat high blood pressure.
- medicines used to treat psychotic symptoms.

How to take BIPHENTIN:

- your healthcare professional will decide the dose that is right for you or your child. Always follow the directions of your healthcare professional and never change your dose or stop taking BIPHENTIN without first discussing it with your healthcare professional.
- BIPHENTIN should be taken once-a-day, with or without food, in the morning.
- a consistent morning routine should be established, with regard to the content and timing of meals.
- BIPHENTIN capsules must be swallowed whole with a full glass of water and should 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.

How to sprinkle BIPHENTIN 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 30 minutes.
 - do not chew the capsule contents (beads).
 - rinse your 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 30 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:

Children/adolescents (6 – 18 years of age) and adults (>18 years of age):

Take the dose prescribed by your doctor. Your doctor may adjust the amount of medicine until it is right for you/your child. From time to time, your doctor may interrupt your treatment with BIPHENTIN to check for symptoms while you/your child are not taking the medicine.

Overdose:

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

Missed Dose:

If you forget to take your 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 BIPHENTIN?

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

Side effects may include:

- headache
- sleeplessness
- drowsiness
- dizziness
- nervousness
- anxiety
- irritability
- loss of appetite
- weight loss, weight gain
- stomach discomfort nausea (feeling sick), vomiting, diarrhea
- increased sweating
- dry mouth
- difficulty opening the mouth (trismus)
- lack of bladder control (incontinence)
- swelling of breast in boys and 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			
Mental Health Problems: 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			✓
Hypertension (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.	✓		
blurred vision		✓	
UNKNOWN			

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	
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
Raynaud's Phenomenon: discolouration of the fingers and toes, pain, sensations of cold and/or numbness		✓	
Serious Allergic Reaction: itching, skin rash, swelling of the mouth, face, lips, or tongue, trouble swallowing, trouble breathing			✓
Seizures or Convulsions: loss of consciousness with uncontrollable shaking			✓
Suicidal Behaviour: thoughts or feelings about harming yourself			✓
Rhabdomyolysis (breakdown of damaged muscle): muscle weakness, muscle pain, muscle spasms, red-brown coloured urine		✓	
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	✓		
Nosebleed	✓		

Slower growth (weight gain and/or height) has been reported with long-term use of methylphenidate in children. Your doctor will be carefully watching your child's height and weight. If you/your child are not growing or gaining weight as your doctor expects, your doctor may stop your/your child's BIPHENTIN treatment.

Tell your doctor if you/your child have blurred vision when taking BIPHENTIN.

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

- Store at room temperature (15°C to 30°C). Protect from moisture.
- Keep unused or expired BIPHENTIN in a secure place to prevent theft, misuse, or accidental exposure.
- Keep out of reach and sight of children and pets.

If you want more information about BIPHENTIN:

- 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 <http://www.elvium.ca>, or by calling 1-800-744-0005.

This leaflet was prepared by Elvium Life Science.

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