Eslicarbazepine (APTIOM ®): the basics

What is eslicarbazepine used for?

Eslicarbazepine has been approved by Health Canada for use:

- on its own to manage focal (partial) onset seizures in adults with epilepsy.
- in combination with other anti-seizure (anti-epileptic) medications to manage focal onset seizures in people above 6 years of age
 who are not adequately controlled with conventional therapy.

Your physician may decide to prescribe this medication for a use different from that approved by Health Canada.

If you have questions about whether this medication is appropriate for you, consult with your physician.

What forms does this medication come in? Is there a generic drug version?

In Canada, eslicarbazepine is sold under the brand name Aptiom®; it is not available as a generic drug.

| Dosage form | Strengths available in Canada | Is it covered by the Ontario Drug Benefit (ODB) program?* |
|---------------|------------------------------------|---|
| Tablets, oral | 200 mg, 400 mg, 600 mg, and 800 mg | Eslicarbazepine is covered by ODB only when specific clinical criteria have |
| | | been met. Consult your healthcare professional for more information. |

^{*}Contact your pharmacist for the most up-to-date information regarding drug availability and coverage.

Before starting eslicarbazepine, inform your healthcare professional of the following:

- your medical history, especially of allergies; heart, kidney, liver, thyroid, or mental health problems; low sodium blood levels; blood disorders; or bone marrow depression
- if you have an allergy or sensitivity to carboxamide derivatives, such as carbamazepine or oxcarbazepine
- if you have the HLA-B*1502 or HLA-A*3101 allele (gene variation)
- if you have a heart conduction or rhythm disorder, such as heart block or atrial fibrillation
- if you have a mixed seizure disorder that includes generalized onset seizures [eslicarbazepine may worsen myoclonic or generalized nonmotor (absence) seizures]
- if you are pregnant, breastfeeding, or considering pregnancy
- any anti-seizure medications you have used in the past
- your current medications (prescription and nonprescription) and any substances you are taking

Eslicarbazepine may interact with the following:

- other anti-seizure medications, such as carbamazepine, phenytoin, and phenobarbital. Your physician may need to adjust the doses of your anti-seizure medications.
- medications and substances that slow down the nervous system (CNS depressants), including alcohol and other anti-seizure
 medications; diuretics ("water pill") and desmopressin; and medications that can affect how your heart beats, such as some
 heart medications and certain anti-seizure medications. These medications can increase your risk of side effects with eslicarbazepine.
- hormonal contraceptives (such as oral contraceptives). These may be less effective when used with eslicarbazepine; consult with your healthcare professional to select the appropriate birth control methods.
- many other medications. This is not a comprehensive list of drug interactions. Inform your healthcare professional about all the
 medicines (prescription and nonprescription) and substances you are taking, including medications from other prescribers, over-thecounter medications, vitamins, minerals, herbal products, or alternative medicines, so they can check for potential drug interactions.
 A potential drug interaction may not rule out use of the medications together; dosage adjustments and/or additional monitoring
 (such as lab work) may be carried out by your healthcare professional; check with your physician or pharmacist.

What are possible side effects from using eslicarbazepine?

Depending on the individual, side effects may occur at varying degrees or not at all, including:

- dizziness, drowsiness, fatigue, and other side effects that can affect your cognition, alertness, coordination, or vision. It is important to avoid activities requiring mental alertness or physical coordination (such as operating hazardous machines or driving) until you are sure that eslicarbazepine does not affect your abilities.
- low sodium levels; underactive thyroid; lower-than-normal numbers of platelets, red blood cells, or white blood cells; and
 liver injury. Your blood work may need to be checked on a regular basis. Long-term use of this medication may decrease bone
 mineral density. Speak with your healthcare professional about osteoporosis prevention.
- heart conduction and rhythm problems. If you have a history of heart disease, tell your physician.
- mood or behaviour changes, like anxiety or depression; thoughts or actions of self-harm may occur rarely. If you or your caregiver/family notice these symptoms or other unusual changes in behaviour or mood, contact your physician.
- rare but serious, life-threatening allergic reactions that affect the skin and mucous membranes, and require immediate medical help. These reactions mostly occur during the first few weeks of therapy. People with the HLA-B*1502 or HLA-A*3101 allele may be at increased risk. If you are of Asian descent, your healthcare professional may check to see if you have the HLA-B*1502 allele, which is common among people of Han Chinese or Southeast Asian descent.

This is not a comprehensive list of possible side effects. Consult with your physician or pharmacist for more information about side effects, including what symptoms to monitor for and what to do about them.

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Tips for using eslicarbazepine (Aptiom®):

- Take your medication as directed by your physician. Read the medication information sheets given to you by your healthcare professional. If you have any questions, ask your physician or pharmacist.
- This medication works best when taken at evenly-spaced intervals, at about the same time each day.
- Eslicarbazepine can be taken with or without food. The tablets can be swallowed whole or crushed. If crushed, your entire dose must be taken soon afterwards; for example, if mixed with a cup of applesauce, that whole cup must be consumed in that sitting.
- If you will be administering this medication to someone else and are pregnant, trying to get pregnant, or breastfeeding, consult your healthcare professional first on how to safely handle the medication.
- If your seizures worsen or you experience new types of seizures, contact your physician.

How will my dose be determined?

In general, your physician will start you on a low dose to decrease the risk of side effects. This dose will be adjusted slowly based on seizure control and any side effects experienced. Other factors such as medical history, potential drug interactions, and, if eslicarbazepine is for a child, body weight will also be taken into consideration when determining your dose.

The usual maintenance dosage range of eslicarbazepine is given below; however, your physician may prescribe a higher or lower dose for you based on the reasons noted above.

| | Usual maintenance dosage range* |
|---|---------------------------------|
| Adults, children above 6 years of age and 40 kg or more | 800 to 1200 mg once daily |
| Children above 6 years of age and under 40 kg | 20 to 30 mg/kg once daily** |

^{*}Your dosage will be individualized based on factors such as indication, medical history, potential drug interactions, clinical response, and tolerability.

What if I miss a dose?

If you miss a dose, take it as soon as you remember. But if it is almost time for your next dose, do not take the missed dose; instead, take your next dose at your usual time. Do not double the dose. If you miss more than 1 dose, contact your healthcare professional for advice.

How do I store this medication?

Store the eslicarbazepine tablets at room temperature (15 to 30°C) in a dry place away from light and heat. Keep out of reach of children.

Medication blood level test - is it required for eslicarbazepine?

Routine monitoring of the concentrations (levels) of eslicarbazepine in your blood is usually not required; however, your healthcare professional may decide to monitor your levels in certain situations such as pregnancy.

Pregnancy and breastfeeding:

- In general, anti-seizure medications may slightly increase the risk of birth defects. It is important to consult with your healthcare
 professional for preconception care if you are planning to become pregnant.
- Folic acid supplementation should be started at least 3 months before pregnancy to reduce the risk of birth defects. Speak with your healthcare professional to determine the appropriate dose for you.
- Your physician may advise you to take vitamin K during the last weeks of your pregnancy to decrease the risk of bleeding complications in your newborn baby.
- Eslicarbazepine may cross the placenta during pregnancy. It passes into the breast milk. The potential benefits of using this medication during pregnancy or breastfeeding must be weighed against any potential risks to your unborn child or breastfeed baby; consult with your physician. Do not stop taking your medication(s) or adjust your dosage on your own.

Warning:

Abrupt withdrawal of any anti-epileptic medication may trigger status epilepticus, a potentially fatal condition of continued seizures without recovery. When there is a need for reduction, discontinuation or substitution of the medication, this should be done gradually and under the physician's care. Never discontinue anti-epileptic medications or make changes in activities unless specifically advised to do so by an attending physician.

This material has been created by Stephanie Chiu, RPh, BCGP, CDE for Epilepsy Toronto in 2024 and is offered to provide general information to the public. It is not intended to be taken as medical advice. Epilepsy Toronto and its advisors accept no liability. Consult your physician and/or neurologist with any questions you may have.

^{**}Consult your child's physician/pharmacist for their specific weight-based dosage.