Stiripentol (DIACOMIT®): the basics

What is stiripentol used for?

Stiripentol has been approved by Health Canada for use in combination with clobazam and valproate to manage refractory generalized tonic-clonic seizures in people with **severe myoclonic epilepsy in infancy** (**Dravet syndrome**) whose seizures are not adequately controlled with clobazam and valproate alone.

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, stiripentol is sold under the brand name Diacomit®; it is not available as a generic drug.

Dosage form	Strengths available in Canada	Is it covered by the Ontario Drug Benefit (ODB) program?*
Capsules, oral	250 mg and 500 mg	Stiripentol is not routinely covered by ODB; coverage may be
Powder for	250 mg/sachet and 500 mg/sachet	considered under exceptional circumstances. Consult your
oral suspension		healthcare professional for more information.

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

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

- your medical history, especially of allergies; kidney, liver, growth, or mental health problems; or blood disorders
- if you are taking carbamazepine, phenytoin, or phenobarbital
- if you are pregnant, breastfeeding, or considering pregnancy
- any anti-seizure (anti-epileptic) medications you have used in the past
- your current medications (prescription and nonprescription) and any substances you are taking

Stiripentol may interact with the following:

- carbamazepine, phenytoin, and phenobarbital. It is not recommended to use stiripentol in combination with these medications for the management of Dravet syndrome.
- clobazam and valproate. Your physician may need to adjust your dose of clobazam and/or valproate.
- theophylline and caffeine. Do not consume medicinal products, food, or beverages containing theophylline or caffeine (such as cola, chocolate, coffee, tea, and energy drinks). See "Tips for using Stiripentol (Diacomit®)". Drinking alcohol while on stiripentol is not recommended.
- medications and substances that slow down the nervous system (CNS depressants), including alcohol and other antiseizure medications. These may increase the risk of side effects, such as drowsiness or slowed breathing.
- many other medications. This is not a comprehensive list of drug interactions. Inform your healthcare professional about all the medicines (prescription and nonprescription) or substances you are taking, including medications from other prescribers, over-the-counter 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 stiripentol?

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

- dizziness, drowsiness, confusion, difficulty concentrating, and other side effects that can affect your cognition, alertness, or coordination. It is important to avoid activities requiring mental alertness or physical coordination (such as operating hazardous machines or driving) until you are sure that stiripentol does not affect your abilities.
- decreased appetite, nausea and weight loss. Keep track of your child's height and weight; tell your physician if you have concerns about their growth.
- lower-than-normal numbers of white blood cells and platelets and elevated liver function tests. Your blood work may need to be checked on a regular basis.
- **delirium and hallucinations**. Although rare in occurrence, these have been reported in adults taking stiripentol. Tell your physician if you or your caregiver/family notice these symptoms.
- mood or behaviour changes, such as hyperexcitability or aggressiveness, which are common side effects for stiripentol; thoughts or actions of self-harm may occur rarely. If you or your caregiver/family notice these symptoms or other unusual changes in behaviour/mood, contact your physician.
- rash. If you experience a rash or other signs of an allergic reaction, seek medical help.

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.

Stiripentol (DIACOMIT®): the basics

Tips for using Stiripentol (Diacomit®):

- 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 times each day.
- Stiripentol should always be taken with food, and not on an empty stomach. It should not be taken with milk or dairy products (such as yogurt), fruit juice, carbonated/fizzy drinks, food or drinks that contain theophylline or caffeine (such as cola, chocolate, coffee, tea, and energy drinks), or alcoholic beverages. Read the list of ingredients to verify the contents of food, beverage, and medicinal products before consuming them.
- The powder for oral suspension should be mixed in a glass of water and taken immediately after mixing during a meal.
- The capsules should be swallowed whole with a glass of water during a meal. Do not break or open the capsule.
- 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 body weight, medical history, and potential drug interactions will also be taken into consideration when determining your dose.

The usual maintenance dosage of stiripentol is 50 mg per kg of body weight per day in 2 or 3 divided doses; however, your physician may prescribe a higher or lower dose for you based on the reasons noted above.

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 stiripentol in its original package 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 stiripentol?

Routine monitoring of the concentrations (levels) of stiripentol in your blood is usually not required.

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.
- There is very limited data on the use of stiripentol during pregnancy or breastfeeding. 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.