

MEDICATION GUIDE
DIACOMIT (die-uh-KA-mit)
(stiripentol)
capsules, for oral use
for oral suspension

Read this Medication Guide before you start taking DIACOMIT and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about DIACOMIT?

DIACOMIT can cause serious side effects, including:

1. Sleepiness and drowsiness. Sleepiness and drowsiness are serious and common side effects. DIACOMIT can make you sleepy or dizzy, and slow your thinking. Your healthcare provider may decrease your dose of clobazam or other seizure medicines.
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how DIACOMIT affects you.
 - Do not drink alcohol or take other medicines that may make you sleepy or dizzy while taking DIACOMIT until you talk to your healthcare provider.
 - DIACOMIT, when taken with alcohol or medicines that cause sleepiness or dizziness, may make your sleepiness or dizziness worse.
2. Loss of appetite and weight loss. Loss of appetite and weight loss are serious and common side effects. DIACOMIT can cause frequent nausea and loss of appetite that can cause weight loss.
 - Your weight should be checked frequently during DIACOMIT treatment.
 - Children who take DIACOMIT should have their weight and growth checked often.
3. Low white blood cell counts (neutropenia) and low platelet counts (thrombocytopenia). Low white blood cell counts may occur during treatment with DIACOMIT and may cause serious infections. Low platelet counts may cause serious bleeding problems. Your healthcare provider should check your white blood cell count and platelet count before and during treatment.
4. Do not stop taking DIACOMIT without first talking to your healthcare provider. Stopping a seizure medicine such as DIACOMIT should be done slowly to avoid having seizures more often, or seizures that do not stop (status epilepticus).
5. Like other antiepileptic drugs, DIACOMIT may cause suicidal thoughts or actions in a very small number of people (about 1 in 500).

Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

Call your healthcare provider right away if you have any of the above side effects while taking DIACOMIT.

What is DIACOMIT?

DIACOMIT is a prescription medicine used along with clobazam to treat seizures in people with Dravet syndrome who are 6 months of age and older and weighing 15 pounds (7 kg) or more.

DIACOMIT has not been shown to be able to treat seizures associated with Dravet syndrome without the use of clobazam. It is not known if DIACOMIT is safe and effective in children under 6 months of age or who weigh less than 15 pounds (7 kg).

Before you take DIACOMIT, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- have phenylketonuria (PKU). **DIACOMIT for oral suspension** contains aspartame. The artificial sweetener may be harmful to people with PKU.
- have or have had depression, mood problems, suicidal thoughts or behavior.
- drink alcohol.
- are pregnant or plan to become pregnant. It is not known if DIACOMIT may harm your unborn baby.
 - Tell your healthcare provider right away if you become pregnant while taking DIACOMIT. You and your healthcare provider will decide if you should take DIACOMIT while you are pregnant.
 - **Pregnancy Registry:** If you become pregnant while taking DIACOMIT, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can register by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicines, including

DIACOMIT, during pregnancy. Information about the registry can be found at the website, <http://www.aedpregnancyregistry.org/>.

- are breastfeeding, or plan to breastfeed. It is not known if DIACOMIT passes into breast milk. Talk to your healthcare provider about the best way to feed your baby while taking DIACOMIT.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking DIACOMIT with certain other medicines can cause side effects or affect how well DIACOMIT or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take DIACOMIT?

- Take DIACOMIT exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much DIACOMIT to take and when to take it.
- DIACOMIT capsules should be swallowed whole with a glass of water during a meal. Do not break or open capsules.
- DIACOMIT for oral suspension should be mixed in a glass of water (100 mL) and should be taken right away after mixing during a meal. To be sure there is no medicine left in the glass, add a small amount of water (25 mL) to the drinking cup and drink all of the mixture. See the complete Instructions for Use on the right way to use DIACOMIT for oral suspension.
- Your healthcare provider may change your dose if needed. Do not change your dose of DIACOMIT without talking to your healthcare provider.
- If you miss a dose of DIACOMIT, take it as soon as you remember. If it is almost time for the next scheduled dose, skip the missed dose and take your next dose at your regular time. Do not take 2 doses of DIACOMIT at the same time.
- If you take too much DIACOMIT, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking DIACOMIT?

- Do not drive, operate heavy machinery, or do other dangerous activities that need you to be alert until you know how DIACOMIT affects you.
- Do not drink alcohol or take other medicines that may make you sleepy or dizzy while taking DIACOMIT without first talking to your healthcare provider.

What are the possible side effects of DIACOMIT?

DIACOMIT may cause serious side effects, including:

- **See “What is the most important information I should know about DIACOMIT?”**

The most common side effects of DIACOMIT include:

- agitation
- loss of control of body movements (ataxia)
- low muscle tone or muscle weakness (hypotonia)
- nausea
- tremor
- trouble saying words clearly (dysarthria)
- trouble sleeping (insomnia)

These are not all the possible side effects of DIACOMIT. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DIACOMIT?

- Store DIACOMIT at room temperature between 68°F to 77°F (20°C to 25°C).
- Store in a dry place in the original package.
- Protect from light.

Keep DIACOMIT and all medicines out of the reach of children.

General information about the safe and effective use of DIACOMIT.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DIACOMIT for a condition for which it was not prescribed. Do not give DIACOMIT to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DIACOMIT that is written for health professionals.

What are the ingredients in DIACOMIT?

Active ingredient: stiripentol

Capsule inactive ingredients: erythrosine (250 mg capsule only), gelatin, indigotine (250 mg capsule only), magnesium stearate, povidone, sodium starch glycolate, titanium dioxide.

For oral suspension inactive ingredients: aspartame, carmellose sodium, erythrosine, glucose, hydroxyethylcellulose, povidone, sodium starch glycolate, sorbitol, titanium dioxide, tutti frutti flavor.

Manufactured by:

BIOCODEX, 1 avenue Blaise Pascal, 60000 BEAUVAIS – France

For more information about DIACOMIT, go to www.biocodex.com or call BIOCODEX at 1-866-330-3050

INSTRUCTIONS FOR USE

DIACOMIT (die-uh-KA-mit)

(stiripentol)

for oral suspension

Be sure that you read, understand, and follow the Instructions for Use before preparing your child's first dose of DIACOMIT for oral suspension and each time you get a refill. There may be new information. This information does not take the place of talking to your child's healthcare provider about their medical condition or treatment. Ask your child's healthcare provider or pharmacist if you have questions about how to mix or give a dose of DIACOMIT for oral suspension.

Important information:

- Your child's healthcare provider will tell you the dose of DIACOMIT and how many packets are needed for your child's dose.
- Each packet of DIACOMIT for oral suspension contains 250 mg or 500 mg of DIACOMIT as a powder. Be sure to use the right strength to prepare your child's dose.
- When you receive DIACOMIT for oral suspension prescription at the pharmacy, check to make sure that you were given the right strength of DIACOMIT for oral suspension, the carton is not damaged, and the packets are not opened.
- Make sure you have enough packets of DIACOMIT for oral suspension to give a full dose. Call your healthcare provider if you need more DIACOMIT for oral suspension. **Do not** run out of your child's medicine.
- Check that the expiration date on the carton (located on the bottom of the carton) and packet (located at the bottom right of the back side of the packet) has not passed. **Do not** use if the expiration date has passed.
- Talk with your child's healthcare provider to help decide the best schedule for giving your child DIACOMIT for oral suspension.
- DIACOMIT for oral suspension must be mixed with water and your child must eat food right after taking DIACOMIT for oral suspension.
- Be sure to give the entire prepared dose of DIACOMIT for oral suspension to your child.
- For more information about DIACOMIT for oral suspension, see the "Medication Guide."

Instructions for mixing DIACOMIT for oral suspension:

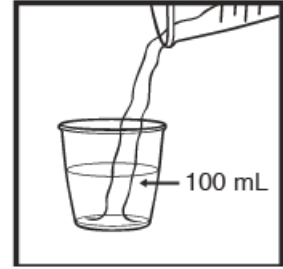
- Before you prepare a dose of DIACOMIT for oral suspension, check the prescription label on the carton for the number of packets you need to prepare a dose.
- Take the prescribed number of packets of DIACOMIT for oral suspension needed for the prescribed dose out of the carton.
- Wash and dry your hands before and after preparing DIACOMIT for oral suspension.
- When preparing DIACOMIT for oral suspension, choose a clean, flat work surface, and place the supplies you will need on the work surface.

Gather the following supplies:

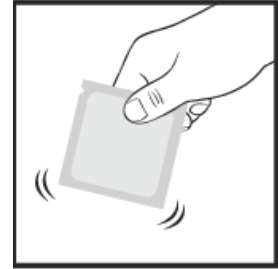
- 1-spoon
- 1-measuring cup
- 1-small drinking cup
- water
- the correct number of DIACOMIT for oral suspension packets needed for the prescribed dose
- 1-clean pair of scissors

Step 1. Fill measuring cup with 100 mL of water.

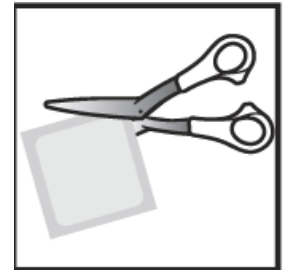
Step 2. Pour 100 mL of water into the small drinking cup.



Step 3. Tap the packet of DIACOMIT for oral suspension to settle the medicine to the bottom of the packet.



Step 4. Using a clean pair of scissors, cut off the top of the packet and make sure the packet is fully open.



Step 5. Empty the packet into the small drinking cup.

- Look inside the packet to make sure there is no medicine left inside.
- If there is medicine left inside, hold the open end of the packet over your small drinking cup and tap the packet again to get all of the medicine out.



To make sure a full dose of DIACOMIT for oral suspension is given, it is important not to spill any medicine and that there is no medicine left in the packet.

Repeat Steps 3 through 5 for each packet of DIACOMIT for oral suspension needed for the total prescribed dose.

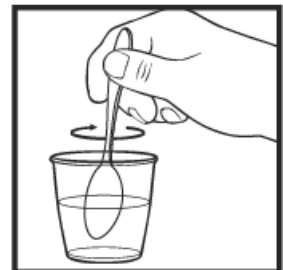
Step 6. Hold the small drinking cup with one hand. With your other hand, use the spoon to gently mix the medicine and the water until clear.

Steps 7 and 8 must be completed right after mixing the medicine.

Step 7. Have your child drink all of the mixture in the small drinking cup.

Step 8. To make sure there is no mixture left in the small drinking cup, add a small amount (25 mL) of water to the small drinking cup:

- Stir with the spoon.
- Repeat Step 7 above.



Step 9. Wash the small drinking cup and spoon. Allow the small drinking cup and spoon to dry. Throw away the empty packet and clean the work surface.

How should I store DIACOMIT for oral suspension?

- Store DIACOMIT for oral suspension at room temperature between 68°F to 77°F (20°C to 25°C) .
- Store in the original package to protect from light.
- **Do not** open DIACOMIT for oral suspension packet until ready to use.
- **Do not** store the DIACOMIT mixture after it is mixed. It must be taken right after mixing.

Keep DIACOMIT for oral suspension and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:
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