DIACOMIT®
(stiripentol) 250 mg, 500 mg
capsules or for oral suspension

DIACOMIT® Discussion Guide

STARTING THE CONVERSATION WITH YOUR CHILD'S DOCTOR ABOUT DIACOMIT

Julia, age 7, actual patient on DIACOMIT

DIACOMIT® (stiripentol)

DIACOMIT® DISCUSSION GUIDE

Deciding whether to make a change to your child's treatment plan can feel daunting. It can help to prepare what you'd like to discuss with your child's doctor during their next appointment. Whether you're ready to make the DIACOMITment or just looking to learn more, we've got you covered. This guide is designed to help you and your child's care team decide if DIACOMIT® (stiripentol) is the right fit for your child. ***Let's get started!***

QUESTIONS FOR YOU

To prepare for the conversation, ask yourself these questions and share your answers with your child's doctor at their next appointment.

1. Which medications is my child taking to manage their seizures associated with Dravet syndrome?

2. What types of seizures are occurring while my child is on these medications? How frequently?

3. What are my goals for my child's treatment plan?

4. Are my treatment goals being met with my child's current treatment plan? What are my hopes for starting a new treatment?

5. What would fewer prolonged seizures mean for my child and my family?

6. Am I ready to make a change? ☐ Yes ☐ No

DIACOMIT (stiripentol) is the **only** FDA-approved treatment developed specifically for seizures associated with Dravet syndrome in children ***as young as 6 months***. It is indicated for children weighing 15 lb or more and taking clobazam.[1]

QUESTIONS FOR YOUR CHILD'S DOCTOR

Now that you've prepared answers on your child's medical history and treatment goals, you're ready to discuss a potential shift in their treatment plan. The following questions can help guide the conversation between you and your child's care team and help determine whether DIACOMIT is the right treatment for your child.

To learn more about treatment with DIACOMIT before your child's next appointment, visit **DIACOMIT.com**.

1. How can DIACOMIT help us achieve our treatment goals?

To learn more about the benefits of DIACOMIT, visit **DIACOMIT.com/about**.

2. Is DIACOMIT (stiripentol) appropriate for my child's treatment plan? ☐ Yes ☐ No

3. Would DIACOMIT interact with other medications my child is taking?

4. How and when would I administer DIACOMIT to my child?

To learn more about dosing and administration, visit **DIACOMIT.com/get-started**.

5. Are there any risks associated with DIACOMIT that I should be aware of and watch out for after my child starts treatment?

To learn more about potential side effects, visit **DIACOMIT.com/about**.

7. When can we expect to see results with DIACOMIT? How long will it take to determine if it is the right treatment for my child?

8. What else should I know about DIACOMIT before starting treatment?

ADDITIONAL QUESTIONS AND NOTES

INDICATION

DIACOMIT (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients taking clobazam who are 6 months of age and older and weighing 7 kg or more. There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

No contraindications are listed.

WARNINGS & PRECAUTIONS

Somnolence

DIACOMIT can cause somnolence. Monitor patients for somnolence, particularly when DIACOMIT is used concomitantly with other CNS depressants or clobazam, which is also known to cause somnolence.

Decreased Appetite and Decreased Weight

DIACOMIT can cause decreases in appetite and weight. The growth and weight of pediatric patients treated with DIACOMIT should be carefully monitored.

Neutropenia and Thrombocytopenia

DIACOMIT can cause significant declines in neutrophil and platelet counts. Hematologic testing should be obtained prior to starting treatment with DIACOMIT and then every 6 months.

Withdrawal Symptoms

As with most antiepileptic drugs (AEDs), DIACOMIT should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus.

Risks in Patients with Phenylketonuria (PKU)

DIACOMIT for oral suspension contains phenylalanine, which can be harmful to patients with PKU. Before prescribing DIACOMIT for oral suspension to a patient with PKU, consider the total daily intake of phenylalanine from all sources, including DIACOMIT for oral suspension. DIACOMIT capsules do not contain phenylalanine.

Suicidal Behavior and Ideation

AEDs, including DIACOMIT, increase the risk of suicidal thoughts or behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

ADVERSE REACTIONS

The most common adverse reactions that occurred in at least 10% of DIACOMIT-treated patients and more frequently than on placebo were somnolence, decreased appetite, agitation, ataxia, decreased weight, hypotonia, nausea, tremor, dysarthria, and insomnia.

PREGNANCY

There are no adequate data on the developmental risks associated with the use of DIACOMIT in pregnant women. Based on animal data, DIACOMIT may cause fetal harm.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AEDs, such as DIACOMIT, during pregnancy. Physicians are advised to recommend that pregnant patients taking DIACOMIT enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry (information at **www.aedpregnancyregistry.org**). This can be done by calling the toll-free number **1-888-233-2334** and must be done by patients themselves or their caregiver.

To report suspected adverse reactions, contact Biocodex at **1-866-330-3050** or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Please see full DIACOMIT Prescribing Information at **www.DIACOMIT.com**.

REFERENCE

1. DIACOMIT® [prescribing information]. Beauvais, France: Biocodex, Inc.; July 2022.

BIOCODEX