What is the DIACOMIT® Difference?

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

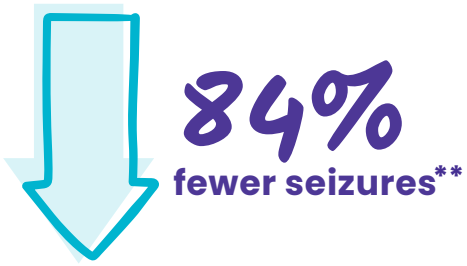
DIACOMIT (stiripentol) offers effective seizure management for patients with Dravet syndrome — earlier than ever before. For children with Dravet, early intervention may help to limit the effects of frequent and prolonged seizures.

Effective Seizure Management Sooner

DIACOMIT is the **only** FDA-approved medication developed specifically for seizures associated with Dravet syndrome in patients **as young as 6 months.***

Most children with Dravet syndrome experience their first seizure before 8 months old.[1, 2] Now, there's treatment available as early as 6 months.

* Indicated for children 15 lb or more and taking clobazam.



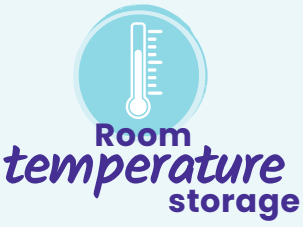
Since 2000, stiripentol (FDA approved as DIACOMIT® in 2018) has brought seizure relief to patients with Dravet. In two clinical studies, DIACOMIT **reduced seizures by 84%**, with almost 39% being seizure-free during the two-month study period.**[3, 4]

Some of the most common adverse events were sleepiness, decreased appetite, agitation, impaired coordination, and decreased weight.

** Median change in seizure frequency

The Convenience Factor

DIACOMIT is available in capsules and fruit-flavored powder for oral suspension. The oral suspension may be helpful for patients who cannot swallow capsules.



Capsules and powder can be stored at room temperature (68°F to 77°F), making it easy to take on the go.

See the DIACOMIT Difference at DIACOMIT.com/hcp

See Indication and Important Safety Information on the reverse side.

Important Safety Information

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

None

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 Prescribing Information at **www.DIACOMIT.com**.

References:

1. Wirrell EC, Laux L, Donner E, et al. Optimizing the diagnosis and management of Dravet syndrome: recommendations from a North American consensus panel. *Pediatr Neurol.* 2017; 68:18-24.
2. Dravet C. Dravet syndrome history. *Dev Med Child Neurol.* 2011;53(suppl 2):1-6.
3. DIACOMIT® [prescribing information]. Beauvais, France: Biocodex, Inc.; July 2022.
4. U.S. Food and Drug Administration. CDER Clinical Review. August 2018. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/206709Orig1s000,207223Orig1s000MedR.pdf. Accessed May 12, 2020.

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