Calculating the Proper Dose

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

DIACOMIT is indicated for patients 6 months and older who weigh 7 kg (15 lb) or more. **The recommended oral dosage is 50 mg/kg/day**, divided into two or three doses (i.e., 16.67 mg/kg three times daily or 25 mg/kg two times daily), depending on your patient's age and weight.

In the event of a missed dose, DIACOMIT should be taken as soon as possible. If it is almost time for the next dose, the patient should not take the missed dose. **Doses should not be doubled.** The total maximum dosage is 3,000 mg/day.

	6 MONTHS TO < 1 YEAR[a,b]	1 YEAR AND OLDER	
BODY WEIGHT	**15 lb +**	**15 lb–22 lb[b]**	**22 lb +**
STEP 1 Convert weight to kilograms	15 lb = **7 kg**	18 lb = **8.2 kg**	30 lb = **13.6 kg**
STEP 2 Multiply by 50 mg	7 kg x 50 mg = **350 mg/day**	8.2 kg x 50 mg = **410 mg/day**	13.6 kg x 50 mg = **680 mg/day**
STEP 3 Round to nearest dose (250 mg increments)	Round up to **500 mg**	Round up to **500 mg**	Round up to **750 mg**
STEP 4 Divide total into 2 or 3 daily doses	Divide into 2 doses/day: **250 mg + 250 mg**	Divide into 2 doses/day: **250 mg + 250 mg**	Divide into 2 doses/day: **250 mg + 500 mg** – OR – Divide into 3 doses/day: **250 mg + 250 mg + 250 mg**

[a] *Dosing frequency should not exceed twice daily to limit free water administration.*
[b] *Dosing frequency should not exceed twice daily to avoid overexposures.*

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.

See additional Important Safety Information on the reverse side.

Side Effect Management

Adjusting the dosage of clobazam or valproate may help manage somnolence and changes in appetite.[1]

Somnolence

- **Reduce clobazam by 25%.** Further reduce by an additional 25% if somnolence persists and adjust dosage of other concomitant anticonvulsant drugs with sedating properties.
- Assess for central nervous system depressants, including alcohol, which may increase risk.

Decreased appetite and decreased weight

- **Reduce valproate by 30% per week.**
- Monitor the weight of patients and the growth rate of pediatric patients.

Additional Dosing Considerations

Other dosage changes can be made to minimize risks and interactions with other substances.[1]

Risks	Recommendations
Phenylketonuria* **DIACOMIT for oral suspension contains phenylalanine, but DIACOMIT capsules do not.*	• **Consider combined daily amount of phenylalanine** from DIACOMIT for oral suspension and all other sources.
Decreased DIACOMIT concentrations due to induction-based interactions	• **Avoid concomitant use of strong inducers or adjust doses.** • These may include CYP1A2, CYP3A4, or CYP2C19 inducers, such as rifampin, phenytoin, phenobarbital, and carbamazepine.
Effects on other drugs	• **Reduce doses of substrates of CYP2C8, CYP2C19, P-gp, and BCPR.** • These may include diazepam or clopidogrel (CYP2C19), carbamazepine (P-gp), and methotrexate, prazosin, or glyburide (BCRP).
Neutropenia and thrombocytopenia	• **Monitor patients for neutropenia or thrombocytopenia.** • Hematologic testing should be obtained prior to starting treatment and then every 6 months.

These are not all the risks for use of DIACOMIT.
Please see Important Safety Information and full Prescribing Information enclosed.

Important Safety Information (cont.)

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 DIACOMIT.com.

Reference

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

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