

RESEARCH MONOGRAPH . COMPOUND PROFILE

Dimiracetam

*A bicyclic 2,5-pyrrolidinedione developed
by Sigma-Tau for chemotherapy-induced
peripheral neuropathy.*

DOCUMENT	KDC-MN-039
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COMPOUND CLASS	Bicyclic dione racetam analog

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ABSTRACT

Dimiracetam (1,4-diazabicyclo[3.3.0]octane-2,5-dione; CAS 126716-03-2; molecular formula C₇H₁₀N₂O₂; molecular weight 154.17) is a bicyclic 2,5-pyrrolidinedione developed by Sigma-Tau (now Defiante Farmaceutica) in Italy with development focused on chemotherapy-induced peripheral neuropathy. The compound is structurally distinct from open-chain racetams in featuring a fused bicyclic scaffold with two carbonyls per ring. Mechanism is incompletely characterized but appears to involve modulation of glutamatergic transmission with NMDA-related effects, distinct from the AMPA potentiation typical of racetams. Phase 2 trials in chemotherapy-induced peripheral neuropathy showed modest reduction in neuropathic pain measures; the program advanced toward Phase 3 but encountered commercial and design challenges. The compound is not approved by any regulatory authority. Limited research-grade availability. Pharmacokinetics: short half-life (1 to 2 hours) and high oral bioavailability. Clinical doses in Phase 2 ranged from 200 to 1600 mg per day in divided administrations.

1. Compound Identification

Dimiracetam is described as bicyclic dione racetam analog. A bicyclic 2,5-pyrrolidinedione developed by Sigma-Tau for chemotherapy-induced peripheral neuropathy.

1.1 Class summary

Bicyclic dione racetam analog

1.2 Subtitle

A bicyclic 2,5-pyrrolidinedione developed by Sigma-Tau for chemotherapy-induced peripheral neuropathy.

2. Abstract

Dimiracetam (1,4-diazabicyclo[3.3.0]octane-2,5-dione; CAS 126716-03-2; molecular formula C₇H₁₀N₂O₂; molecular weight 154.17) is a bicyclic 2,5-pyrrolidinedione developed by Sigma-Tau (now Defiante Farmaceutica) in Italy with development focused on chemotherapy-induced peripheral neuropathy. The compound is structurally distinct from open-chain racetams in featuring a fused bicyclic scaffold with two carbonyls per ring. Mechanism is incompletely characterized but appears to involve modulation of glutamatergic transmission with NMDA-related effects, distinct from the AMPA potentiation typical of racetams. Phase 2 trials in chemotherapy-induced peripheral neuropathy showed modest reduction in neuropathic pain measures; the program advanced toward Phase 3 but encountered commercial and design challenges. The compound is not approved by any regulatory authority. Limited research-grade availability. Pharmacokinetics: short half-life (1 to 2 hours) and high oral bioavailability. Clinical doses in Phase 2 ranged from 200 to 1600 mg per day in divided administrations.

3. Mechanism of Action

Glutamatergic modulation with NMDA-related effects; distinct from typical rac-etam AMPA pharmacology.

The mechanistic profile described above represents the consensus position from peer-reviewed literature where available; for compounds with sparse formal characterization, this section reflects vendor-grade reports and structurally-related class pharmacology and should be interpreted with appropriate caution.

4. Pharmacokinetics and Routes of Administration

Pharmacokinetic data are summarized within the abstract for compounds with formal Phase 1 records. Compounds without published human pharmacokinetic studies are noted as such; investigators should treat the absence of data as a research limitation.

5. Reported Research Dose Ranges

200 to 1600 mg per day in Phase 2 trials.

Doses are scaled from clinical use where the compound is approved as a medicine, from Phase 2/3 trials where development advanced, or from rodent dose-response data scaled by allometric assumptions where the compound has no human clinical record. Investigators should treat dose ranges from research-chemical-grade vendors as starting points for their own pharmacokinetic and tolerability characterization rather than validated dosing recommendations.

6. Sourcing and Quality Verification

Investigators should obtain analytical confirmation of identity (mass spectrometry; for peptides, additionally amino acid analysis or N-terminal sequencing) and purity (HPLC area-percent, ideally greater than 95 percent) on every lot. Vendor certificates of analysis vary in quality; third-party analytical confirmation through independent laboratories (e.g., Janoshik Analytical, Anabolic Lab) is the gold standard for research-grade peptides and small molecules.

For compounds with established pharmaceutical-grade marketing in any jurisdiction, sourcing from the marketed product (where legal and accessible) provides the highest quality assurance.

7. Reconstitution and Handling

Peptides should be reconstituted in bacteriostatic water or sterile water for injection in the volume appropriate to the desired concentration; lyophilized peptides should be allowed to come to room temperature before reconstitution to minimize precipitation. Reconstituted peptides should be stored refrigerated and used within the timeframe specified by the manufacturer (typically 14 to 30 days for bacteriostatic water reconstitutions, shorter for sterile water).

Small molecules: storage conditions vary by compound; consult the certificate of analysis for the specific product. Most are stable at room temperature in dry, dark conditions; oxidation-sensitive compounds (e.g., catecholamine precursors) require cool storage and protection from light.

8. Stack Interaction Considerations

Investigators combining this compound with other research substances should consider receptor-level interactions (additive effects at shared targets), enzyme-level interactions (CYP-mediated drug-drug interactions where applicable), and pharmacodynamic interactions (additive sedation, additive serotonergic activity, additive hemodynamic effects).

The stack interaction section in published monographs of well-characterized compounds is necessarily incomplete for any specific combination; investigators should treat novel combinations with elevated caution and titrate gradually.

9. References

1. Sigma-Tau development program for dimiracetam; Phase 2 chemotherapy-induced peripheral neuropathy results.

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