

73

**A. INGREDIENT NAME:**

**PIRACETAM**

**B. Chemical Name:**

1-Acetamido-2-Pyrrolidinone, Euvicor, Gabacet, Genogris, 2-Ketopyrrolidine-1-Ylacetamide, Nootron, Nootropil, Nootropyl, Normabrain, 2-Oxo-Pyrrolidine-Acetamide, 2-Oxo-Pyrrolidin-1-Ylacetamide, Piracetam, Pirazetam, Pirroxil, Pyracetam, Pyramem, 2-Pyrrolidininnoneacetamide, 2-Pyrrolidoneacetamide, UCB 6215

**C. Common Name:**

**D. Chemical grade or description of the strength, quality, and purity of the ingredient:**

Assay: 99.27%

**E. Information about how the ingredient is supplied:**

White or almost white crystal powder

**F. Information about recognition of the substance in foreign pharmacopeias:**

**G. Bibliography of available safety and efficacy data including peer reviewed medical literature:**

Mondadori, C. Nootropics: Preclinical Results in the Light of Clinical Effects; Comparison with Tacrine. *Critical Reviews™ in Neurobiology*, 1996; 10: 357-370.

Tallal, U., Chase, C., and Russell, G. Calculation of the Efficacy of Piracetam in Treating Information Processing, Reading, and Writing Disorders in Dyslexic Children. *International Journal of Psychophysiology*, 1986; 4: 41-52.

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YaI, V., Derzhiruk, L. P., and Mogilevskii, A. Piracetam-induced changes in the functional activity of neurons as a possible mechanism for the effects of nootropic agents. *Neurosci Behav. Physiol.*, 1996; 26(6): 507-515.

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Di Ianni, M., Wilsher, C. R., and Blank, M. S. The effects of Piracetam in children with dyslexia. *J. Clin Psychopharmacol*. 1985; 5(5): 272-278.

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Dimond, S. J., Scammell, R. E., and Pryce, I. G. Some effects of Piracetam (UCB 6215, Nootropyl) on chronic schizophrenia. *Psychopharmacology*. 1979; 64(3): 341-348.

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## H. Information about dosage forms used:

Patients received either 3.3 g of Piracetam daily or matching placebo syrup. Each dose of test medication was 5 ml. administered before breakfast and again before the evening meal. A 5 ml dose of active medication contained 1.65 g of Piracetam. No dosage adjustments were allowed. The patient's parents were contacted to review dosage instructions and to determine whether any adverse effects had been observed.

## I. Information about strength:

1.65 g -3.3 g

## J. Information about route of administration:

Orally

**K. Stability data:**

**L. Formulations:**

**M. Miscellaneous Information:**

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**TITLE:** Treatment of acute ischemic stroke with piracetam. Members of the Piracetam in Acute Stroke Study (PASS) Group.

**AUTHOR:** De Deyn PP; Reuck JD; Deberdt W; Vlietinck R; Orgogozo JM

**AUTHOR AFFILIATION:** Department of Neurology, Middelheim Hospital, Antwerp, Belgium.

**SOURCE:** Stroke 1997 Dec;28(12):2347-52

**NLM CIT. ID:** 98074088

**ABSTRACT:**

**BACKGROUND AND PURPOSE:** Piracetam, a nootropic agent with neuroprotective properties, has been reported in pilot studies to increase compromised regional cerebral blood flow in patients with acute stroke and, given soon after onset, to improve clinical outcome. We performed a multicenter, randomized, double-blind trial to test whether piracetam conferred benefit when given within 12 hours of the onset of acute ischemic stroke to a large group of patients. **METHODS:** Patients received placebo or 12 g piracetam as an initial intravenous bolus, 12 g daily for 4 weeks and 4.8 g daily for 8 weeks. The primary end point was neurologic outcome after 4 weeks as assessed by the Orgogozo scale. Functional status at 12 weeks as measured by the Barthel Index was the major secondary outcome. CT scan was performed within 24 hours of the onset of stroke but not necessarily before treatment. Analyses based on the intention to treat were performed in all randomized patients (n = 927) and in an "early treatment" population specified in the protocol as treatment within 6 hours of the onset of stroke but subsequently redefined as less than 7 hours after onset (n = 452). **RESULTS:** In the total population, outcome was similar with both treatments (the mean Orgogozo scale after 4 weeks: piracetam 57.7, placebo 57.6; the mean Barthel Index after 12 weeks: piracetam 55.8, placebo 53.1). Mortality at 12 weeks was 23.9% (111/464) in the piracetam group and 19.2% (89/463) in the placebo group (relative risk 1.24, 95% confidence interval, 0.97 to 1.59; P = .15). Deaths were fewer in the piracetam group in those patients in the intention-to-treat population admitted with primary hemorrhagic stroke. Post hoc analyses in the early treatment subgroup showed differences favoring piracetam relative to placebo in mean Orgogozo scale scores after 4 weeks (piracetam 60.4, placebo 54.9; P = .07) and Barthel Index scores at 12 weeks (piracetam 58.6, placebo 49.4; P = .02). Additional analyses within this subgroup, confined to 360 patients with moderate and severe stroke (initial Orgogozo scale score < 55), showed significant improvement on piracetam in both outcomes (P < .02). **CONCLUSIONS:** Piracetam did not influence outcome when given within 12 hours of the onset of acute ischemic stroke. Post hoc analyses suggest that piracetam may confer benefit when given within 7 hours of onset, particularly in patients with stroke of moderate and severe degree. A randomized, placebo-controlled, multicenter study, the Piracetam Acute Stroke Study II (PASS II) will soon begin.

**MAIN MESH  
SUBJECTS:**

Cerebral Ischemia/\*DRUG THERAPY/MORTALITY  
Cerebrovascular Disorders/\*DRUG THERAPY/MORTALITY  
Neuroprotective Agents/ADVERSE EFFECTS/\*THERAPEUTIC USE  
Nootropic Agents/ADVERSE EFFECTS/\*THERAPEUTIC USE  
Piracetam/ADVERSE EFFECTS/\*THERAPEUTIC USE



## **PIRACETAM**

Non-toxic in rodents having an oral LD50 > 10g/kg.

While the toxic properties of piracetam have not been thoroughly investigated it may produce insomnia, psychomotor agitation, nausea, G.I. distress and headache and may enhance the effects of amphetamines, psychotropics and hydergine.

It has been given to children with dyslexia and in people with Alzheimer's disease to increase learning and memory. It may increase muscarinic cholinergic receptors in the brain?



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