

**A. INGREDIENT NAME:**

**CHOLINE BITARTRATE NF XI**

**B. Chemical Name:**

Choline Acid Tartrate, Bitartarato de Colina, 2-Hydroxyethyltrimethylammonium hydrogen tartrate, (2-Hydroxyethyl)trimethylammonium Bitartrate

**C. Common Name:**

Colyne

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

	<i>(Minimum)</i>	<i>(Result)</i>
Assay	98.0%	99.7%

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

White Crystalline Powder, odorless of faint trimethylamine-like order, acid taste, hydroscopic

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

Braz., Ger., Nord., and Port.

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

Fovall, P., Dysken, M. W., and Lazarus, L. W. Choline bitartrate treatment of Alzheimer-type dementia. *Communications in Psychopharmacology*, 1980; 4(2): 141-145.

Beauregard, W. G. Dexpanthenol with choline bitartrate in the treatment of infantile colic. *Journal of the Louisiana State Medical Society*, 1968; 120(3): 142-145.

1998-2454B1\_02\_19-BDL06

**H. Information about dosage forms used:**

Capsules

Tablets

**I. Information about strength:**

Capsules (500mg-2gm)

Tablets (500gm-600gm)

**J. Information about route of administration:**

Orally

**K. Stability data:**

Melts at about 150-151°

**L. Formulations:**

**M. Miscellaneous Information:**



Database: Medline &lt;1966 to present&gt;

Set	Search	Results
1	exp choline/	23968
2	choline bitartrate.tw.	9
3	from 2 keep 2,4,6,8	4

&lt;1&gt;

Unique Identifier

97028826

Authors

Stoll AL. Sachs GS. Cohen BM. Lafer B. Christensen JD.  
Renshaw PF.

Title

Choline in the treatment of rapid-cycling bipolar disorder:  
clinical and neurochemical findings in lithium-treated  
patients.

Source

Biological Psychiatry. 40(5):382-8, 1996 Sep 1.

Abstract

This study examined choline augmentation of lithium for rapid-cycling bipolar disorder. Choline bitartrate was given openly to 6 consecutive lithium-treated outpatients with rapid-cycling bipolar disorder. Five patients also underwent brain proton magnetic resonance spectroscopy. Five of 6 rapid-cycling patients had a substantial reduction in manic symptoms, and 4 patients had a marked reduction in all mood symptoms during choline therapy. The patients who responded to choline all exhibited a substantial rise in the basal ganglia concentration of choline-containing compounds. Choline was well tolerated in all cases. Choline, in the presence of lithium, was a safe and effective treatment for 4 of 6 rapid-cycling patients in our series. A hypothesis is suggested to explain both lithium refractoriness in patients with bipolar disorder and the action of choline in mania, which involves the interaction between phosphatidylinositol and phosphatidylcholine second-messenger systems.

&lt;2&gt;

Unique Identifier

95405204

Authors

Spector SA. Jackman MR. Sabounjian LA. Sakkas C.

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### CHOLINE BITARTRATE TREATMENT OF ALZHEIMER-TYPE DEMENTIAS

Penny Fovall, Maurice W. Dysken, Lawrence W. Lazarus,  
John M. Davis, Robert L. Kahn, Richard Jope,  
Sanford Finkel, Pradeep Rattan  
Research Department  
Illinois State Psychiatric Institute  
Chicago, Illinois 60612  
and  
Department of Psychiatry  
University of Chicago Pritzker School of Medicine  
Chicago, Illinois 60637  
and  
Department of Pharmacology  
UCLA School of Medicine  
Los Angeles, California 90024

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#### Abstract

We conducted a double-blind, placebo controlled study of the effects of choline bitartrate on intellectual performance in 5 patients with early Alzheimer-type dementia. Three doses of choline bitartrate (8 gm, 12 gm, and 16 gm) were given for two weeks each with a two-week placebo period either preceding (N=2) or following (N=3) the drug period. Cognitive testing was administered during a baseline period and thereafter once a week for the duration of the study. Comparing drug condition with placebo, we found significant improvement for auditory and visual word recognition at 12 gm per day of choline bitartrate. The mean plasma choline level nearly doubled from baseline to 12 gm per day. These results suggest improvement in some aspects of cognitive performance during choline bitartrate treatment.

#### Introduction

This paper reports the effects of choline bitartrate on cognitive functioning in early Alzheimer's disease and senile dementia of the Alzheimer type. The impetus for this study came from preliminary neurochemical reports suggesting that choline acetyltransferase (C.A.T.) activity, a possible marker of presynaptic cholinergic neurons, is substantially reduced in areas of cerebral cortex in Alzheimer's disease relative to that of normal age matched controls (1-5). Preliminary studies have raised the possibility that muscarinic acetylcholine receptors are still intact (3-5). This suggests that Alzheimer's disease might involve a selective impairment of the presynaptic cholinergic system (3). Choline treatment, which raises brain acetylcholine, might restore the hypothesized decrement

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No.	Records	Request
1	223	choline
2	125	bitartrate
* 3	3	choline bitartrate

Record 1 of 3 - IPA 1970-3/98

TI: Use of choline in the treatment of ataxia associated with multiple sclerosis

AU: Blattel-RA

SO: Can-Med-Assoc-J (Canadian-Medical-Association-Journal); 1979; 121(Dec 22); 1568

PY: 1979

AB: Two ataxic patients with multiple sclerosis were given lemonade with or without 5 g choline bitartrate daily in a double-blind crossover study for 30 days. One patient had significant increase in ability to stand on one leg.

AN: 17-02236

Record 2 of 3 - IPA 1970-3/98

TI: Choline therapy in Alzheimer's disease

AU: Smith-CM; Swash-M; Exton-Smith-AN; Philips-MJ; Overstall-PW; et-al

SO: Lancet (Lancet); 1978; 2(Aug 5); 318

PY: 1978

AB: The effectiveness of choline bitartrate (I) therapy in the treatment of Alzheimer's disease was assessed in 10 patients. All patients received 2 weeks' treatment with I (9 g/day) and 2 weeks' treatment with a placebo. There was a wash out period of one week in between. Tests were selected or devised to suite the residual abilities of the patients. No significant differences between I and placebo emerged on any of the tests; nevertheless, 3 patients seemed less confused after 2 weeks of I treatment. It was concluded that these results, even though not encouraging, should not rule out the possible benefits of I treatment.

AN: 16-0066

Record 3 of 3 - IPA 1970-3/98

TI: Clinical effects of choline in Alzheimer's disease

AU: Etienne-P; Gauthier-S; Johnson-G; Collier-B; Mendis-T; et-al

SO: Lancet (Lancet); 1978; 1(Mar 4); 508-509

PY: 1978

AB: The effects of choline bitartrate, 8 g/day dissolved in water and added to orange juice, over 4 weeks on Alzheimer's disease were studied in 3 patients. No definite clinical or laboratory signs of improvement were found.

AN: 15-2661



## **CHOLINE BITARTRATE**

Oral LD50 for human estimated to be 200-400 g.

Its toxicology has not been thoroughly investigated. It can produce eye, skin and pulmonary irritation, dizziness, nausea, blurred vision, lengthened P-R interval (?), clinical depression.

Has been used in Alzheimer's type dementias.



## REFERENCES

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2. Spector SA, Jackman MR, Sabounjian LA, et al. Effects of choline supplementation on fatigue in trained cyclists. *Med Sci Sports Exerc* 1995; 27(5):668-73.
3. Fovall P, Dysken MW, Lazarus LW, et al. Choline bitartrate treatment of Alzheimer-type dementias. *Commun Psychopharmacol* 1980; 4(2):141-5.
4. Beauregard WG. Dextranthenol with choline bitartrate in the treatment of infantile colic. *J La State Med Soc* 1968; 120(3):142-5.
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7. Hauser DC, Levandowsky M, Glassgold JM. Ultrasensitive chemosensory responses by a protozoan to epinephrine and other neurochemicals. *Science* 1975; 190(4211):285-6.
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9. Smith CM, Swash M, Exton-Smith AN, et al. Choline therapy in Alzheimer's disease. *Lancet* 1978; 2(Aug 5):318.
10. Etienne P, Gauthier S, Johnson G, et al. Clinical effects of choline in Alzheimer's disease. *Lancet* 1978; 1(Mar 4):508-9.