

Candidates for Bulk Drug List - FDA Modernization Act
Pharmacy Compounding

Bulk Drug Information

Ingredient Name: **Taurine**

Chemical Name: 2-aminoethanesulfonic acid

Common Name: Taurine

Chemical Grade: Per specifications attached

How Supplied: Powder

Foreign Pharmacopeia Status: Is not listed in EP nor JP

Submitted previously to USP: Unknown

Safety and Efficacy data bibliography: See reference list and abstracts attached

Compounded Product Information

Dosage Form: Sterile Injectable Solution

Strength: 2% to 5% solution of Taurine in Sterile Water for Injection to be further diluted with Total Parenteral Nutrition (TPN) Solution prior to administration for a total dose of 5 mg to 10 mg/ Kg body wt/ day

Route of Administration: Intravenous (IV)

Information on past and proposed uses; rationale for use: See attached articles

Why not use commercially available source?: Not available as a commercially available sterile solution supplement

Stability Data: Conservatively given 2 weeks expiration dating at refrigerated temperatures based on fact taurine is used in commercially available pediatric amino acid formulations and given 18 months expiration dating. Taurine is not currently available as a sterile solution supplement.

1998-345431-02-40-BDL07

ADDITIONAL TESTING

Manufacturer's Name and
Manufacturing Location

Must be documented and agree with Lot
Uniformity sheet. Documentation must be
maintained as a part of the record.

Certificate of Analysis

Must accompany each lot received and be
maintained as a part of the record.

*Carried out by Abbott Incoming Drug Inspection Department according to
departmental procedures.

NOTE: If desiccant bags are required in each container, the desiccant bags must not
contact the raw drug material. They must be placed outside of the liner in the
raw drug container. Desiccant bags may not be made of fiber generating
materials. The number of desiccant bags must be identified on the outside of
each container.

Packing and Marking: Pack, mark and label in accordance with all applicable
regulations.

References (cont)

23. Dorvil NP, Yousef IM, Tuchweber B. Taurine Prevents Cholestasis Induced by Lithocholic acid Sulfate in Guinea Pigs. *Am J Clin Nutr* 1983; 37:221-32.
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28. Azuma J, Sawamura A, Awata N et al. Double-Blind Randomized Crossover Trial of Taurine in Congestive Heart Failure. *Curr Ther Res* 1983; 34(4):543-57.

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TITLE: Taurine in infant nutrition.
AUTHOR: Karan S
AUTHOR AFFILIATION: Department of Pediatrics, Niloufer Hospital for Women and Children, Red Hills, Hyderabad.
SOURCE: Indian J Pediatr 1991 May-Jun;58(3):311-6
NLM CIT. ID: 92039901
ABSTRACT: The importance of taurine in diet is poorly understood. The present evidence suggests that it is a conditionally essential aminoacid in man wherein deficiency states may result in adverse changes which will be improved with supplementation. It has a role in fat absorption in preterm infants and children with cystic fibrosis, retinal dysfunction in patients receiving TPN and those with blind loop gut syndromes. Taurine is also reported to improve maturation of ABER in pre-term infants and has a role in osmoregulation of CNS and may act as neuroinhibitor.

MAIN MESH SUBJECTS: *Diet
 *Infant Nutrition
 *Taurine/DEFICIENCY/METABOLISM/PHYSIOLOGY

ADDITIONAL MESH SUBJECTS: Human
 Infant

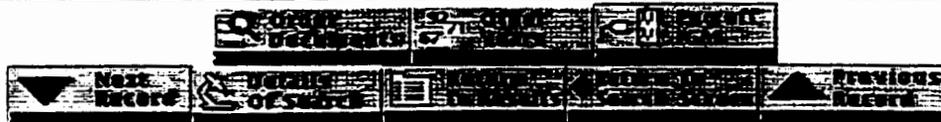
PUBLICATION TYPES: JOURNAL ARTICLE
 REVIEW
 REVIEW, TUTORIAL

LANGUAGE: Eng
REGISTRY NUMBERS: 107-35-7 (Taurine)

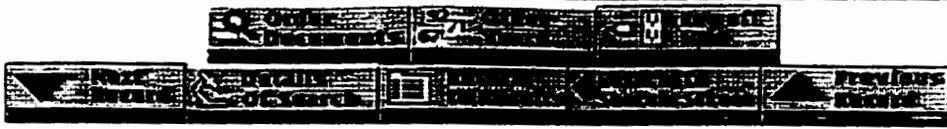


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PUBLICATION CLINICAL TRIAL
TYPES: JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL
LANGUAGE: Eng
REGISTRY 107-35-7 (Taurine)
NUMBERS: 60-27-5 (Creatinine)



NUMBERS: 4371-52-2 (Cysteine)
7005-18-7 (Methionine)



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TITLE: Early metabolic treatment after liver transplant: amino acid tolerance.

AUTHOR: Iapichino G; Radrizzani D; Bonetti G; Codazzi D; Colombo A; Gridelli B; Langer M; Ronzoni G; Savioli M

AUTHOR AFFILIATION: Istituto Anestesiologia e Rianimazione dell'Universita, IRCCS Ospedale Maggiore, Milano, Italy.

SOURCE: Intensive Care Med 1995 Oct;21(10):802-7

NLM CIT. ID: 96128631

ABSTRACT: **OBJECTIVE:** We investigated the amino acid (AA) tolerance during Total Parenteral Nutrition (TPN) in adult patients undergone liver transplant (LTX). **DESIGN:** The treatment (Glucose and AA), induced on the 2nd postoperative day, was later maintained with 27 kcal/kg Ideal Body Weight (IBW) as glucose and 0.12 (12 patients: protocol #1), 0.18 (10 patients: protocol #2) and 0.25 g nitrogen (N)/kg IBW (13 patients: protocol #3) till end of the 6th postoperative day. The N intake was sequentially modified in protocol #2 and #3 to increase the supply of the amino acid (AA) that resulted in an infusion plasma level below the expected "normal" range (between 1 and 1.6 times the overnight fasting plasma level of volunteer). **PATIENTS:** 35 consecutive adult patients without diabetes and organ failures for the entire study period. **MEASUREMENTS:** Plasma AA profile was measured before LTX and at the last TPN day under continuous infusion. During #1 and #2 protocol, many AA resulted below or at the lower range of the norm while, during 0.25 gN/kg IBW infusion, the majority of the administered AA significantly increased with respect to reference values. Nevertheless, they remained in the "normal" plasma range indicating that they were supplied in an optimal amount (particularly the aromatic and sulphurated ones, potentially toxic if liver function is impaired, and the branched chain AA (BCAA) given at consistent dosage: 0.5 g/kg). Arginine resulted significantly increased (Arg: 1.9 times the reference) and cystine (Cys: 0.45), serine (Ser: 0.8) and taurine (Tau: 0.85) remained significantly lower than "normal" as well as the not administered citrulline (Cit: 0.58) and alfa amino butyric acid (Aba: 0.41). The AA (and calorie) load almost balanced the N losses during the 5th (0.411 +/- 0.038) and 6th study day (0.305 +/- 0.019 gN/kg). **CONCLUSIONS:** 0.25 gN/kg could be considered the minimum N load in the uncomplicated adult LTX recipients, for reassuring a balanced plasma AA pattern and body N turnover in the early postoperative phase.

MAIN MESH SUBJECTS: Amino Acids/ANALYSIS/*BLOOD/*THERAPEUTIC USE
*Energy Intake
Liver Transplantation/*ADVERSE EFFECTS/*PHYSIOLOGY
Parenteral Nutrition, Total/*METHODS

ADDITIONAL Adolescence

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TITLE: Taurine induces a long-lasting increase of synaptic efficacy and axon excitability in the hippocampus.

AUTHOR: Galarreta M; Bustamante J; Martin del Rio R; Solis JM

AUTHOR AFFILIATION: Departamento de Investigacion, Hospital Ramon y Cajal, Madrid, Spain.

SOURCE: J Neurosci 1996 Jan;16(1):92-102

NLM CIT. ID: 96110785

ABSTRACT: The physiological role of taurine, one of the most abundant free amino acids in the mammalian brain, is still poorly understood. We have found that bath application of the amino acid taurine induces two opposite actions on field excitatory synaptic potentials (fEPSP) recorded in the CA1 area of hippocampal slices: a decrease in fEPSP slope prevented by GABAA antagonists, and a long-lasting potentiation of fEPSP independent of GABAA or NMDA receptor activation. Two long-lasting processes account for this taurine-induced potentiation: (1) an increase in synaptic efficacy that is accompanied neither by modifications in the basic postsynaptic membrane electrical properties nor by those presynaptic changes involved in fEPSP paired-pulse facilitation; and (2) an increase in the axon excitability revealed by a reduction on the threshold for antidromic action potential activation. In addition, taurine perfusion also induces a long-lasting increase in intracellularly recorded EPSPs and monosynaptically activated IPSPs. A number of experimental observations such as temperature dependence, extracellular Na⁺ concentration dependence, and saturation studies, although they are not unequivocally conclusive, suggest that the taurine uptake system is required for the taurine-induced fEPSP potentiation. Our data describe a new taurine action defined as a potentiation of synaptic transmission due in part to an increment in presynaptic axon excitability and in synaptic efficacy.

MAIN MESH SUBJECTS: Axons/*PHYSIOLOGY/ULTRASTRUCTURE
Hippocampus/CYTOLOGY/*PHYSIOLOGY
Synaptic Transmission/*PHYSIOLOGY
Taurine/PHARMACOLOGY/*PHYSIOLOGY

ADDITIONAL MESH SUBJECTS: Animal
Drug Synergism
Electrophysiology
Evoked Potentials/PHYSIOLOGY
Female
Membrane Potentials/PHYSIOLOGY
Potassium Channels/ANTAGONISTS & INHIB
Rats
Rats, Sprague-Dawley

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TITLE: [Role of taurine in neutrophil function]

AUTHOR: Masuda M; Horisaka K; Koeda T

SOURCE: Nippon Yakurigaku Zasshi 1984 Sep;84(3):283-92

NLM CIT. ID: 85052750

ABSTRACT: The influence of taurine on neutrophil phagocytic and bactericidal capacities and lysosomal enzyme-releasing ability was evaluated in the present study using neutrophils obtained from casein-elicited rat peritoneal exudates. Taurine was dissolved in drinking water at a concentration of 0.3%, and the solution was given to rats for 1-21 days (460 mg/kg/day). Taurine concentration in the serum increased with the term of its administration, while in the neutrophils, it increased significantly after administration for 1 or 3 days. When administered for 7 or 10 days, however, no difference was noted from the control group, but then the concentration remarkably increased after 21 days of administration. The bactericidal capacity of the neutrophils against *Escherichia coli* was strengthened as their concentration of taurine increased; phagocytic capacity was also strengthened. The release of myeloperoxidase following phagocytosis of yeasts increased with administration, while the release of beta-glucuronidase, lysozyme and lactate dehydrogenase, which are induced by N-formylmethionyl-leucyl-phenylalanine, were inhibited. The hypotonic hemolysis of erythrocytes was also inhibited. Taurine decreased the fluorescence depolarization of diphenylhexatriene, indicating an increase in membrane fluidity. These results suggested that taurine strengthens both phagocytic and bactericidal capacities of neutrophils by increasing the fluidity of neutrophil membrane and membrane stability and thus plays an important role in the mechanism of host defense.

MAIN MESH SUBJECTS: *Blood Bactericidal Activity/DRUG EFFECTS
Neutrophils/ENZYMOLOGY/*PHYSIOLOGY
Taurine/BLOOD/PHARMACOLOGY/*PHYSIOLOGY

ADDITIONAL MESH SUBJECTS: Animal
Cell Membrane/DRUG EFFECTS/PHYSIOLOGY
English Abstract
Lysosomes/ENZYMOLOGY
Male
Membrane Fluidity/DRUG EFFECTS
Phagocytosis/DRUG EFFECTS
Rats
Rats, Inbred Strains

PUBLICATION JOURNAL ARTICLE TYPES:

LANGUAGE: Jpn

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TITLE: Taurine in the nutrition of the human infant.
AUTHOR: Gaul GE
SOURCE: Acta Paediatr Scand Suppl 1982;296:38-40
NLM CIT. ID: 83123119
ABSTRACT: The precise biological role of taurine is unknown apart from its conjugation with bile acids and xenobiotics. Evidence is accumulating, however, that taurine may have a more general biological role in development and membrane stability. Furthermore, there is a dietary requirement for taurine in the human infant. Whether or not it is "essential" in man, awaits further study.

MAIN MESH SUBJECTS: Infant Food/*ANALYSIS
*Infant, Premature
Milk, Human/*ANALYSIS
Taurine/*ADMINISTRATION & DOSAGE/METABOLISM

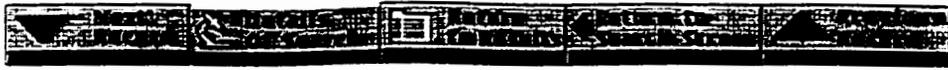
ADDITIONAL MESH SUBJECTS: Animal
Cats
Human
Infant, Newborn
Nutritional Requirements

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Eng
REGISTRY NUMBERS: 107-35-7 (Taurine)



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Title

Taurine-supplemented total *parenteral nutrition* and *taurine* status of malnourished cancer patients.

Author

Gray GE; Landel AM; Meguid MM

Address

Department of Surgery' University Hospital' SUNY Health Science Center' Syracuse 13210.

Source

Nutrition, 10(1):11-5 1994 Jan-Feb

Abstract

The status of plasma *taurine* and whether its concentration can be influenced by total *parenteral nutrition* (TPN) was determined in 51 malnourished fasting cancer patients after surgery and 7-14 days after starting TPN providing 41 +/- 2 kcal' 0.30 +/- 0.02 g N kg⁻¹.day⁻¹ and 40 mg pyridoxine. Plasma *taurine* was 50% lower in patients than in control subjects. Plasma *taurine* was significantly greater than baseline only after 14 days of TPN. We also studied the effects of surgery and *taurine* supplementation (8.6 mg.kg⁻¹.day⁻¹) on plasma and urine *taurine* concentrations in 12 malnourished patients. Preoperatively' all patients had normal plasma *taurine* concentrations; postoperatively' it was in the deficient range in 4 patients. *Taurine*-supplemented patients initially had higher than baseline concentrations; by day 10' none had subnormal levels. Subnormal *taurine* concentrations commonly occur in malnourished postoperative cancer patients; surgery further precipitates their fall. Plasma concentrations were maintained only with *taurine*-supplemented TPN.

Language

Eng

Unique Identifier

94257924

MESH Headings

Adult 1 I; Aged 1 I; Cysteine 1 I BL; Female 3 I; Human 3 I; Male 3 I; Methionine 1 I BL; Middle Age 1 I; Neoplasms 1 I BL/*CO; *Nutrition* Disorders 1 I BL/*CO/*TH; *Parenteral Nutrition*' Total 1 I /*MT; Support' Non-U.S. Gov't 3 I; *Taurine* 1 I *AD/*BL/DF

Publication Type

CLINICAL TRIAL; JOURNAL ARTICLE; RANDOMIZED CONTROLLED TRIAL

ISSN

0899-9007

Country of Publication

UNITED STATES

TAURINE

Dose in literature of 5 to 10 mg/kg/day. Found in high amounts in brain where it may act to modify neural transmission (GABA?). Also conjugates with drugs for excretion. It may work with glycine in the spinal cord.

Used in infant nutrition (i.v.) and in long term total parenteral nutrition (TPN) to normalize taurine plasma and blood cell concentration.

Appears non-toxic since the rodent acute LD50 is >5 g/kg but decreased activity and respiratory depression was seen. Reported to decrease muscle strength in chickens.

REFERENCES

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