

Candidates for Bulk Drug List - FDA Modernization Act
Pharmacy Compounding

Bulk Drug Information

Ingredient Name: **Glutamine**

Chemical Name: 2-aminoglutaramic acid

Common Name: Glutamine

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 attached summaries

Compounded Product Information

Dosage Form: Sterile Injectable Solution

Strength: Approximately 2% solution of Glutamine in Sterile Water for Injection to be further diluted with Total Parenteral Nutrition (TPN) Solution prior to administration for a total dose of 25 mg to 400 mg/ Kg body wt/ day

Route of Administration: Intravenous (IV)

Information on past and proposed uses; rationale for use: See attached articles and JPEN, Volume 14 (No.4), Julv-August 1990 Supp.: pages 39S - 146S.

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

Stability Data: See attached article. Conservatively assigned 2 weeks expiration dating at refrigerated temperatures. The data suggests that at 4 weeks held at 8 degrees C there is less than 5% change.

1998-3454B1_02-27-BDL14

FOR AJINOMOTO U. S. A., INC.

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MAY. 24. 1994

PRODUCT DATA

AJINOMOTO CO., INC.
KAWASAKI PLANT
1-1 SUZUKI-CHO KAWASAKI-KU
KAWASAKI-CITY JAPAN

ANALYTICAL RESULTS OF L-GLUTAMINE

LOT NO. 301AABZ

Identification	:	Passed test	
Specific rotation (D-LINE, 20°)	:	35.3 °	
		AJI TEST1 dried sample. C=2. 6N HCl	
State of solution (Transmittance)	:	NOT LESS THAN	98.0 %
		AJI TEST2 0.4g in 20ml of H2O, spectrophotometer, 430nm, 10mm cell thickness	
State of solution	:	Clear & colorless	
Chloride(Cl)	:	NOT MORE THAN	0.020 %
Ammonium(NH4)	:	NOT MORE THAN	0.10 %
Sulfate(SO4)	:	NOT MORE THAN	0.020 %
Iron(Fe)	:	NOT MORE THAN	10 PPM
Heavy metals(Pb)	:	NOT MORE THAN	10 PPM
Arsenic(As2O3)	:	NOT MORE THAN	1 PPM
Other amino acids	:	Passed test	
		AJI TEST9 test sample: 30MCG, D-2-d control: L-Glu(NH2) 0.12MCG	
Loss on drying	:	0.01 %	
		AJI TEST11 at 105° for 3hours	
Residue on ignition (sulfated)	:	0.01 %	
Assay	:	100.3 %	
PH	:	5.7	
		AJI TEST33 1.0g in 50ml of H2O	

2.8

MAIN MESH *Critical Care
SUBJECTS: Dipeptides/*ADMINISTRATION & DOSAGE/BLOOD
Multiple Trauma/BLOOD/*THERAPY
*Parenteral Nutrition, Total
ADDITIONAL Adult
MESH Amino Acids/BLOOD
SUBJECTS: Comparative Study
Dose-Response Relationship, Drug
Drug Administration Schedule
Energy Intake/PHYSIOLOGY
Female
Glutamine/BLOOD
Human
Male
Middle Age
PUBLICATION CLINICAL TRIAL
TYPES: JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL
LANGUAGE: Eng
REGISTRY 0 (Amino Acids)
NUMBERS: 0 (Dipeptides)
13115-71-4 (glycylglutamine)
56-85-9 (Glutamine)



Order Documents	Other Years	Log off IGM		
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Human
Infant, Newborn
Male
Prospective Studies
Support, Non-U.S. Gov't

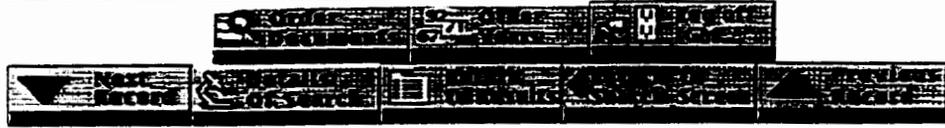
PUBLICATION TYPES: **CLINICAL TRIAL**
JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL

LANGUAGE: **Eng**
REGISTRY NUMBERS: **56-85-9 (Glutamine)**
56-86-0 (Glutamic Acid)



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Treatment Outcome
PUBLICATION CLINICAL TRIAL
TYPES: JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL
LANGUAGE: Eng
REGISTRY 56-85-9 (Glutamine)
NUMBERS:



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TITLE: Historical perspective on nutritional support of cancer patients [editorial; comment]

AUTHOR: Copeland EM 3rd

SOURCE: CA Cancer J Clin 1998 Mar-Apr;48(2):67-8

NLM CIT. ID: 98183365

COMMENT: CA Cancer J Clin 1998 Mar-Apr;48(2):69-80

ABSTRACT: Initially, total parenteral nutrition (TPN) was not used in cancer patients because of the fear of sepsis and the potential for stimulation of tumor growth. It was used first in cancer patients who had failed all attempts at enteral nutrition and in whom adequate anticancer therapy would have been otherwise impossible. TPN candidates today remain patients with responsive tumors who cannot tolerate the toxicity of cancer therapy because they are malnourished.

MAIN MESH SUBJECTS: Neoplasms/DRUG THERAPY/PHYSIOPATHOLOGY/*THERAPY

ADDITIONAL MESH SUBJECTS: *Parenteral Nutrition, Total/ADVERSE EFFECTS/INSTRUMENTATION
Antineoplastic Agents/PHARMACOLOGY/THERAPEUTIC USE
Catheterization, Central Venous/ADVERSE EFFECTS/INSTRUMENTATION
Catheters, Indwelling/ADVERSE EFFECTS
Enteral Nutrition
Glutamine/ADMINISTRATION & DOSAGE/THERAPEUTIC USE
Human
Nutrition Disorders/THERAPY
Patient Selection
Sepsis/ETIOLOGY

PUBLICATION COMMENT:

TYPES: EDITORIAL

LANGUAGE: Eng

REGISTRY: 0 (Antineoplastic Agents)

NUMBERS: 56-85-9 (Glutamine)



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ADDITIONAL MESH SUBJECTS: *Parenteral Nutrition, Total
Rectal Neoplasms/*SURGERY
ADDITIONAL MESH SUBJECTS: Adult
Aged
Aged, 80 and over
Amino Acids/BLOOD
Double-Blind Method
Female
Human
Length of Stay
Lymphocyte Count
Male
Middle Age
Postoperative Period
Stress/METABOLISM
Support, Non-U.S. Gov't
PUBLICATION TYPES: CLINICAL TRIAL
JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL
LANGUAGE: Eng
REGISTRY NUMBERS: 0 (Amino Acids)
0 (Dipeptides)
39537-23-0 (alanylglutamine)



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TITLE: Effect of glutamine-enriched total parenteral nutrition on small intestinal gut-associated lymphoid tissue and upper respiratory tract immunity.

AUTHOR: Li J; Kudsk KA; Janu P; Renegar KB

AUTHOR AFFILIATION: Department of Surgery, University of Tennessee at Memphis, USA.

SOURCE: Surgery 1997 May;121(5):542-9

NLM CIT. ID: 97287061

ABSTRACT: **BACKGROUND:** Our prior work shows that total parenteral nutrition (TPN) causes small intestinal gut-associated lymphoid tissue (GALT) atrophy, lowers small intestinal immunoglobulin A (IgA) levels, and impairs secretory IgA-mediated mucosal immunity of the upper respiratory tract. These experiments examine whether an isonitrogenous 2% glutamine-enriched TPN solution prevents these changes. **METHODS:** Institute of Cancer Research mice were randomized to chow (chow), intravenous feeding of a TPN solution (TPN), or glutamine-enriched TPN (glutamine) groups. After mice were fed for 5 days, lymphocytes were isolated from Peyer's patches, the intraepithelial layer, and lamina propria to determine cell yields and phenotypes. Total small intestinal IgA levels were analyzed by means of enzyme-linked immunosorbent assay. In a second series of experiments, mice underwent intranasal inoculation with H1N1 virus to establish immunity. After 3 weeks mice were randomized to chow, TPN, or glutamine groups. After feeding for 5 days, mice were rechallenged with intranasal virus and killed at 40 hours to determine viral shedding from the upper respiratory tract. **RESULTS:** Total lymphocyte yield in the Peyer's patches, the intraepithelial layer, and lamina propria, small intestinal IgA levels, and the CD4+/CD8+ ratio in the lamina propria decreased with TPN but remained normal with glutamine. On rechallenge, 87% of the mice in the TPN group shed virus in nasal secretions, whereas only 38% of the glutamine-treated group ($p < 0.05$ versus TPN) and 7.1% of the chow group ($p < 0.002$ versus TPN) were virus positive. **CONCLUSIONS:** Isonitrogenous supplementation of TPN with 2% glutamine improves IgA-mediated protection in the upper respiratory tract and normalizes GALT populations.

MAIN MESH SUBJECTS: Glutamine/ADMINISTRATION & DOSAGE/*PHARMACOLOGY
Nasal Mucosa/DRUG EFFECTS/*IMMUNOLOGY
*Parenteral Nutrition, Total
Peyer's Patches/DRUG EFFECTS/*IMMUNOLOGY

ADDITIONAL MESH SUBJECTS: Animal
IgA/ANALYSIS
Lymphocyte Count
Mice

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TITLE: Glutamine and intestinal immune cells in humans.

AUTHOR: van der Hulst RR; von Meyenfeldt MF; Tiebosch A; Buurman WA; Soeters PB

AUTHOR AFFILIATION: Department of Surgery, University of Limburg, Maastricht, The Netherlands.

SOURCE: JPEN J Parenter Enteral Nutr 1997 Nov-Dec;21(6):310-5

NLM CIT. ID: 98069200

ABSTRACT: **BACKGROUND:** Total parenteral nutrition (TPN) is associated with depletion of intestinal immune cells and increased gut permeability (GP). Adding glutamine (GLN) to TPN preserves GP by an unknown mechanism. Intestinal immune cells situated between the enterocytes (intraepithelial lymphocytes, [IEL]) influence GP in vitro. To obtain insight into the underlying mechanism of GLN on GP, we investigated the effects of GLN-supplemented TPN on IEL, immunoglobulin A (IgA) plasma cells and goblet cells, and enterocyte proliferation in intestinal biopsies. **METHODS:** Twenty patients randomly received GLN-enriched TPN (GT) or isonitrogenous standard TPN (ST). Proliferation and number of immune cells were measured in intestinal biopsies obtained before and after 10 days of TPN. **RESULTS:** No change in proliferative activity or in number of IgA plasma cells was observed. Goblet cells increased in the ST group, whereas the change seen in the GT group did not reach significance. In the GT group, IEL decreased, whereas in the ST group, no change in the number of IEL was observed. **CONCLUSIONS:** TPN was not associated with changes in proliferative activity or with depletion of gut immune cells. The data indicate that GLN-supplemented TPN has a different effect on intestinal immune cells compared with standard TPN.

MAIN MESH SUBJECTS: Epithelial Cells/*DRUG EFFECTS/METABOLISM
Glutamine/*PHARMACOLOGY
IgA/*BIOSYNTHESIS
Intestinal Mucosa/*DRUG EFFECTS/PATHOLOGY
Lymphocytes/*DRUG EFFECTS/METABOLISM
*Parenteral Nutrition
Plasma Cells/*DRUG EFFECTS/METABOLISM

ADDITIONAL MESH SUBJECTS: Adolescence
Adult
Aged
Amino Acids/PHARMACOLOGY
Antibody Formation/DRUG EFFECTS
Cell Division/DRUG EFFECTS
Comparative Study

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TITLE: Glycyl-L-glutamine-enriched total parenteral nutrition maintains small intestine gut-associated lymphoid tissue and upper respiratory tract immunity.

AUTHOR: Li J; King BK; Janu PG; Renegar KB; Kudsk KA

AUTHOR AFFILIATION: Department of Surgery, University of Tennessee at Memphis 38163, USA.

SOURCE: JPEN J Parenter Enteral Nutr 1998 Jan-Feb;22(1):31-6

NLM CIT. ID: 98100306

ABSTRACT: **BACKGROUND:** i.v. administration of a total parenteral nutrition (TPN) solution results in small intestinal gut-associated lymphoid tissue (GALT) atrophy, lowers small intestinal immunoglobulin A (IgA) levels, and impairs upper respiratory tract secretory IgA-mediated mucosal immunity; isonitrogenous supplementation of TPN with 2% glutamine attenuates these changes. This experiment examines whether a 2% glycyl-L-glutamine-enriched TPN solution reverses i.v. TPN-induced changes as effectively as L-glutamine. **METHODS:** Male Institute of Cancer Research (ICR) mice underwent intranasal inoculation with H1N1 influenza virus to establish immunity. After 3 weeks, mice were randomized to chow, i.v. feeding of a TPN solution, glutamine-enriched TPN, or glycyl-L-glutamine-enriched TPN. After 4 days of feeding, mice were challenged intranasally with influenza virus and killed at 40 hours to determine viral shedding from the respiratory tract; normal convalescent mice do not shed virus because they possess intact IgA-mediated mechanisms. Lymphocytes were isolated from Peyer's patches, the intraepithelial layer, and lamina propria to determine cell yields. **RESULTS:** Total lymphocyte yield in the Peyer's patches, the intraepithelial layer, and lamina propria decreased with TPN but remained normal with glutamine and glycyl-L-glutamine. Upon challenge, 70% of the mice in the TPN group shed virus in nasal secretions, whereas only 20% of the glutamine-treated group, 18% of glycyl-L-glutamine group and none of the Chow group were virus positive. **CONCLUSIONS:** L-Glutamine and glycyl-L-glutamine have similar effects on i.v. administered TPN-associated (GALT) atrophy and decreased upper respiratory tract immunity.

MAIN MESH SUBJECTS: Dipeptides/*ADMINISTRATION & DOSAGE
Intestine, Small/*IMMUNOLOGY
*Parenteral Nutrition, Total
Peyer's Patches/CYTOLOGY/*IMMUNOLOGY/PATHOLOGY
Respiratory System/*IMMUNOLOGY
Virus Shedding/*IMMUNOLOGY

ADDITIONAL MESH SUBJECTS: Animal
Animal Nutrition
Comparative Study

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TITLE: Brief clinical report: glutamine-enriched total parenteral nutrition in a patient with radiation-induced renal and intestinal fibrosis.

AUTHOR: Wicke C; Gottwald T; Becker HD

AUTHOR AFFILIATION: Department of General Surgery, University of Tübingen, Germany.

SOURCE: Nutrition 1996 Nov-Dec;12(11-12 Suppl):S85-6

NLM CIT. ID: 97129619

ABSTRACT: This brief clinical report illustrates the case of a 50-y-old male patient with severe radiation-induced renal and intestinal fibrosis who received glutamine-enriched total parenteral nutrition (TPN). The patient had end-stage renal disease and, therefore, underwent a kidney transplant. In the postoperative course the patient developed signs of bowel obstruction and cachexia. He received two courses of glutamine-enriched TPN before he underwent surgery for small bowel stenosis. Postoperatively, the patient received a third course of glutamine-enriched TPN. During the patient's hospital course the following indexes were monitored: patient's weight, serum concentrations of protein, albumin, and triacylglycerol. Intestinal permeability was assessed with the lactulose-mannitol sugar test (L-M test). We measured changes in the patient's weight and the L-M test. We hypothesize that glutamine-enriched TPN may have been beneficial in the hospital course of this critically ill patient and may have influenced the patient's intestinal function and permeability.

MAIN MESH SUBJECTS: Glutamine/*ADMINISTRATION & DOSAGE
Intestines/*PATHOLOGY/RADIATION EFFECTS
Kidney/*PATHOLOGY/RADIATION EFFECTS
*Parenteral Nutrition, Total
*Radiation Injuries

ADDITIONAL MESH SUBJECTS: Case Report
Fibrosis
Human
Kidney Failure, Chronic/SURGERY
Kidney Transplantation
Male
Middle Age

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Eng

REGISTRY NUMBERS: 56-85-9 (Glutamine)

GLUTAMINE

It is reported to enhance intestinal function and improve the immune response in humans. Given in TPN to humans. No toxicity information has been found in the literature although excessive oral doses have produced diarrhea. Like taurine, it conjugates with drugs for excretion.

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