

Table 3, an adverse event must have occurred in more than 10% of subjects in any treatment group.

Table 3 - Controlled Trial Adverse Events—Initial 4 Week Treatment Period

Adverse Experiences	Group A	Group B	Group C
	rhGH+SOD ¹ N=16 n(%)	rhGH+SOD[GLN] ¹ N=16 n(%)	SOD [GLN] ¹ N=9 n(%)
Total Number of Subjects with At Least One AE	16 (100)	16 (100)	8 (89)
Body as a Whole:	15 (94)	15 (94)	4 (44)
General Disorders			
Edema, Peripheral	11 (69)	13(81)	1 (11)
Edema, Facial	8 (50)	7(44)	0 (0)
Pain	3 (19)	1(6)	1 (11)
Chest Pain	3 (19)	0 (0)	0 (0)
Fever	0 (0)	1(6)	2 (22)
Back Pain	1 (6)	0 (0)	1 (11)
Flu-like Disorder	0 (0)	1 (6)	1 (11)
Malaise	2 (13)	0 (0)	0 (0)
Edema, Generalized	2 (13)	0 (0)	0 (0)
Abdomen, Enlarged	0 (0)	0 (0)	1 (11)
Allergic Reaction	0 (0)	0 (0)	1 (11)
Rigors (Chills)	0 (0)	0 (0)	1 (11)
Gastrointestinal System Disorders	12 (75)	12 (75)	6 (67)
Flatulence	4 (25)	4 (25)	2 (22)
Abdominal Pain	4 (25)	2 (13)	1 (11)
Nausea	2 (13)	5 (31)	0 (0)
Tenesmus	1 (6)	3 (19)	3 (33)
Vomiting	3 (19)	3 (19)	1 (11)
Hemorrhoids	1 (6)	0 (0)	1 (11)
Mouth Dry	1 (6)	0 (0)	1 (11)
Musculoskeletal System Disorders	7 (44)	7 (44)	1 (11)
Arthralgia	7 (44)	5 (31)	0 (0)
Myalgia	2 (13)	0 (0)	1 (11)
Resistance Mechanism Disorders	6 (38)	3 (19)	4 (44)
Infection	0 (0)	1 (6)	3 (33)
Infection Bacterial	3 (19)	0 (0)	1 (11)
Infection Viral	1 (6)	2 (13)	0 (0)
Moniliasis	2 (13)	0 (0)	0 (0)
Application Site Disorders	5 (31)	4 (25)	1 (11)
Injection Site Reaction	3 (19)	4 (25)	1 (11)
Injection Site Pain	5 (31)	0 (0)	0 (0)
Central and Peripheral Nervous System Disorders	4 (25)	4 (25)	2 (22)
Dizziness	1 (6)	2 (13)	0 (0)
Headache	1 (6)	1 (6)	1 (11)
Hypoesthesia	1 (6)	1 (6)	1 (11)
Skin and Appendages Disorders	4 (25)	4 (25)	2 (22)
Rash	1 (6)	2 (13)	0 (0)
Pruritis	0 (0)	1 (6)	1 (11)
Sweating Increased	2 (13)	0 (0)	0 (0)
Nail Disorder	0 (0)	0 (0)	1 (11)
Respiratory System Disorders	1 (6)	5 (31)	1 (11)
Rhinitis	0 (0)	3 (19)	1 (11)
Metabolic and Nutritional Disorders	3 (19)	1 (6)	1 (11)
Dehydration	3 (19)	0 (0)	1 (11)
Thirst	0 (0)	0 (0)	1 (11)
Urinary System Disorders	2 (13)	1 (6)	1 (11)
Pyelonephritis	0 (0)	0 (0)	1 (11)
Psychiatric Disorders	1 (6)	0 (0)	2 (22)
Depression	0 (0)	0 (0)	2 (22)
Reproductive Disorders, Female	2 (13)	0 (0)	1 (11)
Breast Pain, Female	1 (6)	0 (0)	1 (11)
Hearing and Vestibular Disorders	0 (0)	2 (13)	0 (0)
Ear or Hearing Symptoms	0 (0)	2 (13)	0 (0)

¹SOD[GLN] = Specialized Oral Diet supplemented with Glutamine; rhGH+SOD = Human Growth Hormone plus Specialized Oral Diet; rhGH + SOD [GLN] = Human Growth Hormone plus Specialized Oral Diet supplemented with Glutamine

Group A: rh-GH + SOD for 4 weeks followed by SOD for 12 weeks.
Group B: rh-GH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12

weeks.
Group C: rh-GH placebo + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks

Table 4 summarizes the number of subjects by system-organ class who experienced an adverse event during weeks 5 to 18 of the randomized, controlled SBS study. To be listed in Table 4, an adverse event must have occurred in more than 10% of subjects in any treatment group.

Table 4—Controlled Trial Adverse Events - Weeks 5 to 18

Adverse Experiences	Group A	Group B	Group C
	rhGH+SOD ¹ N=15 n(%)	rhGH+SOD [GLN] ¹ N=16 n(%)	SOD[GLN] ¹ N=9 n(%)
Total Number of subjects with At Least One AE	12 (80)	13 (81)	7 (78)
Gastrointestinal System Disorders	7 (47)	7 (44)	3 (33)
Nausea	3 (20)	0 (0)	2 (22)
Vomiting	2 (13)	3 (19)	0 (0)
Abdominal Pain	3 (20)	1 (6)	0 (0)
Tenesmus	0 (0)	3 (19)	1 (11)
Pancreatitis	0 (0)	1 (6)	1 (11)
Constipation	0 (0)	0 (0)	1 (11)
Crohn's Disease Aggravated	0 (0)	0 (0)	1 (11)
Gastric Ulcer	0 (0)	0 (0)	1 (11)
Gastrointestinal Fistula	0 (0)	0 (0)	1 (11)
Resistance Mechanism Disorders	6 (40)	5 (31)	5 (56)
Infection Bacterial	0 (0)	2 (13)	3 (33)
Infection Viral	3 (20)	1 (6)	1 (11)
Infection	1 (7)	2 (13)	1 (11)
Sepsis	3 (20)	1 (6)	0 (0)
Body as a Whole: General Disorders	4 (27)	2 (13)	1 (11)
Fever	2 (13)	1 (6)	1 (11)
Fatigue	2 (13)	0 (0)	0 (0)
Respiratory System Disorders	2 (13)	4 (25)	1 (11)
Rhinitis	1 (7)	3 (19)	0 (0)
Laryngitis	0 (0)	0 (0)	1 (11)
Pharyngitis	0 (0)	0 (0)	1 (11)
Reproductive Disorders, Female	0 (0)	4 (25)	1 (11)
Vaginal Fungal Infection	0 (0)	0 (0)	1 (11)
Skin and Appendages Disorders	2 (13)	2 (13)	1 (11)
Rash	1 (7)	0 (0)	1 (11)
Musculoskeletal System Disorders	2 (13)	2 (13)	0 (0)
Arthralgia	2 (13)	2 (13)	0 (0)
Psychiatric Disorders	0 (0)	1 (6)	1 (11)
Depression	0 (0)	0 (0)	1 (11)
Insomnia	0 (0)	0 (0)	1 (11)
Urinary System Disorders	0 (0)	0 (0)	2 (22)
Pyelonephritis	0 (0)	0 (0)	1 (11)
Renal Calculus	0 (0)	0 (0)	1 (11)
Application Site Disorders	0 (0)	0 (0)	1 (11)
Injection Site Reaction	0 (0)	0 (0)	1 (11)
Liver and Biliary System Disorders	0 (0)	0 (0)	1 (11)
Hepatic Function Abnormal	0 (0)	0 (0)	1 (11)
Vascular Extracardiac Disorders	0 (0)	0 (0)	1 (11)
Vascular Disorder	0 (0)	0 (0)	1 (11)

Group A: rh-GH + SOD for 4 weeks followed by SOD for 12 weeks.
Group B: rh-GH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.
Group C: rh-GH placebo + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks

¹SOD[GLN] = Specialized Oral Diet supplemented with Glutamine; rhGH+SOD = Human Growth Hormone plus Specialized Oral Diet; rhGH + SOD [GLN] = Human Growth Hormone plus Specialized Oral Diet supplemented with Glutamine

The safety profile in patients receiving oral glutamine with growth hormone was similar to the safety profile in patients receiving growth hormone without glutamine. During the initial 4 week treatment period, 100% of patients receiving growth hormone with and without glutamine reported at least one adverse event (AE), whereas 89% of patients receiving growth hormone placebo with glutamine reported at least one AE. During weeks 5 to 18, 81% of patients receiving growth hormone with glutamine, 80% of patients receiving growth hormone without glutamine and 78% of patients receiving growth hormone placebo with glutamine experienced at least one AE. There were no deaths in this study.

OVERDOSAGE

Single oral doses of glutamine at about 20-22 g/kg, 8-11 g/kg, and 19 g/kg were lethal in mice, rats, and rabbits, respectively.

DOSAGE AND ADMINISTRATION

NutreStore™ should be administered as a cotherapy with recombinant human growth hormone [see the package insert for somatotropin (rDNA origin) for injection for full prescribing information] followed by continued NutreStore™ for up to 16 weeks.

The recommended dosage of NutreStore™ is 30 g daily in divided doses (5 g taken 6 times each day orally) for up to 16 weeks. Each dose of NutreStore™ (5g) should be reconstituted in 8-oz (250-mL) of water prior to consumption.

NutreStore™ should be taken with meals or snacks at 2- to 3-hour intervals while awake. The volume of water may be varied according to the patient's preference. In the event of a patient's transient intolerance to oral intake, a dose may be delayed for up to 2 hours. The safety and efficacy of NutreStore™ have not been studied beyond 16 weeks of treatment.

HOW SUPPLIED

NutreStore™ is supplied in preprinted paper-foil-plastic laminate packets containing 5 g of L-glutamine powder.

STORAGE

NutreStore™ (L-glutamine powder for oral solution) should be stored at 25°C (77°F) with excursions allowed to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

For additional information concerning NutreStore™, contact:



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