HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NUTRESTORE® safely and effectively. See full prescribing information for NUTRESTORE.

NUTRESTORE (L-glutamine) powder for oral solution
Initial U.S. Approval: 2004

----------INDICATIONS AND USAGE----------
NUTRESTORE is an amino acid indicated for:
- the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support when used in conjunction with a recombinant human growth hormone that is approved for this indication (1)

----------DOSAGE AND ADMINISTRATION----------
- 30 g daily in divided doses (5 g taken 6 times each day orally) for up to 16 weeks (2)
- Each dose should be reconstituted in 8 oz (250 mL) of water prior to consumption (2)
- Should be taken with meals or snacks at 2- to 3-hour interval while awake (2)

----------DOSAGE FORMS AND STRENGTHS----------
- Pre-printed paper-foil-plastic laminate packets: 5 g powder (3)

----------CONTRAINDICATIONS----------
- None (4)

----------WARNINGS AND PRECAUTIONS----------
- Routine monitoring of renal and hepatic function is recommended in patients receiving IPN, particularly in those with renal or hepatic impairment (5.1)

----------ADVERSE REACTIONS----------
Most common adverse reactions are (6.1):
- In initial four (4) weeks (incidence >10%): flatulence, abdominal pain, nausea, tenesmus, vomiting, hemorrhoids, mouth dry.
- In weeks 5-18 (incidence >10%): nausea, vomiting, tenesmus, pancreatitis, constipation, Crohn's disease aggravated, gastric ulcer, gastrointestinal fistula.

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2020

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

NUTRESTORE [L-glutamine powder for oral solution] is indicated for the treatment of Short Bowel Syndrome (SBS) in patients receiving specialized nutritional support when used in conjunction with a recombinant human growth hormone that is approved for this indication [see *Dosage and Administration (2)*].

NUTRESTORE and recombinant human growth hormone (rhGH) therapy should be used in conjunction with optimal management of SBS. Optimal management of SBS may include a specialized oral diet, enteral feedings, parenteral nutrition, fluid and micronutrient supplements. A specialized oral diet may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences.

Routine monitoring of renal and hepatic function is recommended in patients receiving NUTRESTORE and intravenous parenteral nutrition (IPN), particularly in those with renal or hepatic impairment. Glutamine is metabolized to glutamate and ammonia, which may increase in patients with hepatic dysfunction.

The safety and efficacy of NUTRESTORE have not been studied beyond 16 weeks of treatment.

2 DOSAGE AND ADMINISTRATION

NUTRESTORE should be administered as a cotherapy with rhGH (see prescribing information for somatropin [rDNA origin] for injection) 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 (5 g) 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.

3 DOSAGE FORMS AND STRENGTHS

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

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Increased Serum Ammonia and Glutamate

Glutamine is metabolized to glutamate and ammonia, which may increase in patients with hepatic dysfunction. Therefore, routine monitoring of renal and hepatic function is recommended in patients receiving intravenous parenteral nutrition (IPN) and NUTRESTORE, particularly in those with renal or hepatic impairment.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Table 1 provides the number of subjects by system-organ class experiencing at least one adverse reaction during the 4-week treatment period of the SBS study. To be listed in Table 1, an adverse reaction must have occurred in more than 10% of subjects in any treatment group.

Table 1. Controlled Trial Adverse Reactions – Initial 4-Week Treatment Period

Adverse Reactions	Group A rhGH+SOD[1] N=16 n (%)	Group B rhGH+SOD[GLN][1] N=16 n (%)	Group C SOD[GLN][1] N=9 n (%)
Total Number of Subjects with At Least One Adverse Reaction	16 (100)	16 (100)	8 (89)
Body as a Whole: General Disorders	**15 (94)**	**15 (94)**	**4 (44)**
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)
Hypoasthesia	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)

[1] SOD [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: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.
GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.
GROUP C: rhGH placebo + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

Table 2 summarizes the number of subjects by system-organ class who experienced an AR during weeks 5 to 18 of the randomized, controlled SBS study. To be listed in Table 2, an AR must have occurred in more than 10% of subjects in any treatment group.

Table 2. Controlled Trial Adverse Reactions –Weeks 5 to 18

Adverse Reactions	Group A rhGH+SOD[1] N=15 n (%)	Group B rhGH+SOD[GLN][1] N=16 n (%)	Group C SOD[GLN][1] N=9 n (%)
Total Number of Subjects with At Least One Adverse Reaction	**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)

[1] SOD [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
GROUP A: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.
GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.
GROUP C: rhGH placebo + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.

During the initial 4-week treatment period, 100% of patients receiving growth hormone with and without glutamine reported at least one AR, whereas 89% of patients receiving growth hormone placebo with glutamine reported at least one AR. 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 AR. There were no deaths in this study.

7 DRUG INTERACTIONS

Formal drug interaction studies have not been conducted.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on NUTRESTORE use in pregnant persons to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies were not conducted with NUTRESTORE.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

Endogenous glutamine is present in human milk. There is no information on the effects of NUTRESTORE on the breastfed infant or the effect on milk production. The developmental and health benefits from breastfeeding should be considered along with the mother's clinical need for NUTRESTORE and any potential adverse effects on the breastfed infant from NUTRESTORE or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of L-glutamine in pediatric patients have not been established.

8.5 Geriatric Use

The clinical trial enrolled SBS patients between the ages of 20 and 75 years. Only 8 of the 41 subjects evaluated were ≥65 years of age. The clinical trial of oral glutamine did not include sufficient numbers of subjects aged 65 years and over to determine if they respond differently than younger subjects. In general, dose selection for an elderly patient should be individualized, because of the greater frequency of decreased hepatic, renal, or cardiac function, as well as concomitant disease in this population.

8.6 Hepatic Impairment

Glutamine is metabolized to glutamate and ammonia, which may increase in patients with hepatic dysfunction. Therefore, routine monitoring of hepatic function is recommended in patients receiving intravenous parental nutrition (IPN) and NUTRESTORE.

8.7 Renal Impairment

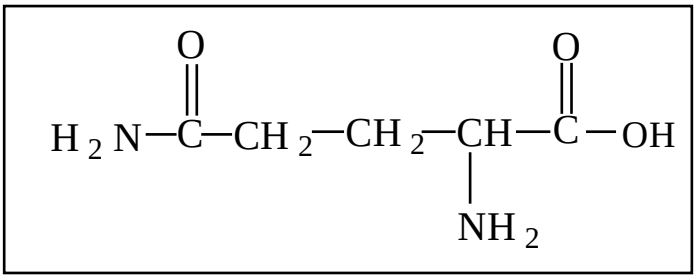
Glutamine is metabolized to glutamate and ammonia. Routine monitoring of renal function is recommended in patients receiving intravenous parental nutrition (IPN) and NUTRESTORE.

10 OVERDOSAGE

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

11 DESCRIPTION

NUTRESTORE (L-glutamine powder for oral solution) for oral administration is formulated as a white crystalline powder in a paper-foil-plastic laminate packet. Each packet of NUTRESTORE contains 5 g of L-glutamine. The amino acid glutamine is also known as (S)-2-aminoglutaramic acid, L-glutamic acid 5-amide, (S)-2,5-diamino-5-oxopentanoic acid, or L-glutamine. The molecular formula of glutamine is $C_5H_{10}N_2O_3$, and the molecular weight is 146.15 d. Glutamine has the following structural formula:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

L-glutamine has important functions in regulation of gastrointestinal cell growth, function, and regeneration. Under normal conditions, glutamine concentration is maintained in the body by dietary intake and synthesis from endogenous glutamate. Data from clinical studies indicate that the role of and nutritional requirements for glutamine during catabolic illness, trauma, and infection may differ significantly from the role of and nutritional requirements for glutamine in healthy individuals. Glutamine concentrations decrease and tissue glutamine metabolism increases during many catabolic disease states, and thus glutamine is often considered a "conditionally essential" amino acid.

12.2 Pharmacodynamics

When glutamine was administered in combination with rhGH to rats, villous height, bowel growth, plasma insulin-like growth factor I, and body weight were significantly higher than in rats treated with either glutamine or rhGH alone.

12.3 Pharmacokinetics

The pharmacokinetics of L-glutamine as described below are based on literature data in healthy subjects. The pharmacokinetics in patients with SBS have not been determined. The plasma glutamine concentrations in these patients following oral administration are expected to be highly variable depending on the length, segment, and presence/absence of ileal-cecal valve for the remnant bowel.

Absorption

Following single dose oral administration of glutamine at 0.1 g/kg to six subjects, mean peak blood glutamine concentration was 1028 µM (or 150 mcg/mL) occurring approximately 30 minutes after administration. The pharmacokinetics following multiple oral doses have not been adequately characterized.

Distribution

After an intravenous bolus dose in three subjects, the volume of distribution was estimated to be approximately 200 mL/kg.

Metabolism
Endogenous glutamine participates in various metabolic activities, including the formation of glutamate, and synthesis of proteins, nucleotides, and amino sugars. Exogenous glutamine is anticipated to undergo similar metabolism.

Elimination
Metabolism is the major route of elimination for glutamine. Although glutamine is eliminated by glomerular filtration, it is almost completely reabsorbed by the renal tubules. After an IV bolus dose in three subjects, the terminal half life of glutamine was approximately 1 hour.

Specific Populations
There are no studies to determine the effect of race, age, or gender on the pharmacokinetics of L-glutamine.

Drug Interaction Studies
No drug-drug interaction studies have been conducted. Because metabolism of glutamine is mediated via non-CYP enzymes, glutamine pharmacokinetics are unlikely to be affected by other agents through CYP enzyme inhibition or induction.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of L-glutamine. Studies to evaluate its potential for impairment of fertility or its mutagenic potential have not been conducted.

14 CLINICAL STUDIES

14.1 Short Bowel Syndrome
A randomized, controlled, 3-arm, double-blind, parallel-group clinical study evaluated the efficacy and safety of oral glutamine as a cotherapy with rhGH in subjects with SBS who were dependent on intravenous parenteral nutrition (IPN) for nutritional support. The primary endpoint was the change in weekly total IPN volume defined as the sum of the volumes of IPN, supplemental lipid emulsion (SLE), and intravenous hydration fluid. The secondary endpoints were the change in weekly IPN caloric content and the change in the frequency of IPN administration per week.

All subjects received a specialized oral diet (SOD) for the duration of the study. Following a two-week equilibration period, treatment was administered in a double blind manner. Group A (N=16) received rhGH for four weeks plus oral glutamine placebo for 16 weeks, Group B (N=16) received rhGH for four weeks plus oral glutamine for 16 weeks, and Group C (N=9), received rhGH placebo for four weeks plus oral glutamine for 16 weeks. The efficacy of glutamine was assessed by comparing the cotherapy (rhGH and oral glutamine) to rhGH alone.

After 4 weeks of treatment with subcutaneous rhGH (0.1 mg/kg/d) and oral glutamine (30 g/d) (Group B), subjects with SBS reduced their requirement for IPN volume (-7.7 L/wk), IPN caloric content (-5751 kcal/wk), and weekly frequency of IPN administration (-4.2 d/wk).

Table 3. Results for Endpoints after 4 weeks of Treatment

	Group A rhGH + SOD[1]	Group B rhGH + SOD[GLN][1]	Group C SOD[GLN][1]
Total IPN volume (L/wk)			
Mean at Baseline	**10.3**	**10.5**	**13.5**
Mean Change	**-5.9**	**-7.7***	**-3.8**
Total IPN Calories (kcal/wk)			
Mean at Baseline	**7634.7**	**7895.0**	**8570.4**
Mean Change	**-4338.3**	**-5751.2**	**-2633.3**
Frequency of IPN or SLE (days/week)			
Mean at Baseline	**5.1**	**5.4**	**5.9**
Mean Change	**-3.0**	**-4.2**	**-2.0**

[1] SOD[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
*p= 0.023, treatment comparison between rhGH + SOD[GLN] versus rhGH+SOD
GROUP A: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.
GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.
GROUP C: rhGH placebo + SOD[GLN] for 4 weeks followed by SOD[GLN] for 12 weeks

IPN volume requirements were significantly reduced in subjects receiving subcutaneous rhGH and oral glutamine (Group B) when compared with IPN volume requirements in subjects receiving either treatment alone.

Table 4. Persistence of Treatment Effect

Change in IPN* Volume, Calories, and Frequency Week 2 to Week 18 ITT Population			
Endpoint	**Group A [n = 16]**	**Group B [n = 16]**	**Group C [n = 9]**
Change in weekly IPN Volume (L/wk)	-5.9	-7.2	-4.7
Change in weekly IPN Calories (kcal/wk)	-3522.2	-5347.3	-2254.0
Change in weekly IPN frequency (days/wk)	-2.9	-3.9	-1.9

*IPN is Total IPN excluding supplemental lipid emulsion (SLE) and hydration fluid.
GROUP A: rhGH + SOD for 4 weeks followed by SOD for 12 weeks.
GROUP B: rhGH + SOD [GLN] for 4 weeks followed by SOD [GLN] for 12 weeks.
GROUP C: rhGH placebo + SOD[GLN] for 4 weeks followed by SOD[GLN] for 12 weeks.

The change in weekly IPN volume, calories and frequency was assessed from Week 2 to Week 18. The data support that the treatment effect is maintained for 16 weeks. The efficacy of oral glutamine beyond 16 weeks of treatment has not been adequately studied.

16 HOW SUPPLIED/STORAGE AND HANDLING

NUTRESTORE is supplied in preprinted paper-foil-plastic laminate packets containing 5 g of L-glutamine powder and is supplied as follows:

- Carton of 84 packets (NDC 42457-001-84)

Store at 25°C (77°F) with excursions allowed to 15°to 30°C (59°to 86°F). [See USP Controlled Room Temperature]

17 PATIENT COUNSELING INFORMATION

[See FDA-approved patient labeling]

17.1 Dosing Instructions

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.

For additional information concerning NUTRESTORE, contact:

Manufactured for:

Emmaus MEDICAL, INC.

21250 Hawthorne Blvd., Suite 800
Torrance, CA 90503
Tel: 1-877-420-6493
www.nutrestore.com

Patient Information
NUTRESTORE® (NOO-tre-stor)
(L-glutamine)
powder for oral solution

Please read this Patient Information leaflet carefully before you start taking NUTRESTORE and each time you get a refill. There may be new information. The information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is NUTRESTORE?

NUTRESTORE is a prescription medicine used along with a human growth hormone to treat Short Bowel Syndrome (SBS) in people receiving a special diet tailored to meet their needs.
It is not known if NUTRESTORE is safe and effective in children.

Before taking NUTRESTORE, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- are older than 65 years of age. Your dose of NUTRESTORE may need to be changed.
- are pregnant or plan to become pregnant. It is not known if NUTRESTORE can harm your unborn baby.
- are breastfeeding or plan to breastfeed. NUTRESTORE can pass into your breastmilk. Talk to your healthcare provider about the best way to feed your baby if you take NUTRESTORE.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take NUTRESTORE?

- Take NUTRESTORE exactly as your healthcare provider tells you to take it.
- NUTRESTORE should be taken up to 6 times a day (every 2 to 3 hours during the day) with a meal or snack.
- Pour the contents of 1 NUTRESTORE packet into an 8-ounce glass (1 cup) of water and stir for 1 minute. Drink the NUTRESTORE mixture within 2 hours.
- If you miss a dose, take your next dose as soon as you remember or as soon as you are able to take it.
- Do not take more than 6 packets of NUTRESTORE each day.

What are the possible side effects of NUTRESTORE?

NUTRESTORE may cause serious side effects, including:

- **An increase in blood ammonia and glutamate levels.** You may have an increase in your blood ammonia and glutamate levels when receiving intravenous parenteral nutrition (IPN). This increase in blood ammonia and glutamate can affect your liver and kidneys. Your healthcare provider may do blood tests to check your liver and kidney function while you are taking NUTRESTORE.

The most common side effects of NUTRESTORE include:

during the first 4 weeks of treatment:

- gassiness
- stomach (abdominal) pain
- nausea
- painful bowel movements
- vomiting
- hemorrhoids
- dry mouth

during 5 to 18 weeks of treatment:

- nausea
- vomiting
- painful bowel movements
- swelling of pancreas
- constipation
- Crohn's disease worsened
- stomach (gastric) ulcer
- opening between stomach and intestine

These are not all the possible side effects of NUTRESTORE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NUTRESTORE?

- Store NUTRESTORE at room temperature between 68°F to 77°F (20°C to 25°C).

Keep NUTRESTORE and all medicines out of the reach of children.

General information about the safe and effective use of NUTRESTORE

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use NUTRESTORE for a condition for which it was not prescribed. Do not give NUTRESTORE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about NUTRESTORE that is written for health professionals.

What are the ingredients in NUTRESTORE?

Active ingredients: L-glutamine

Manufactured by: Emmaus Medical, Inc. 21250 Hawthorne Blvd., Suite 800 Torrance, CA 90503
For additional information go to www.nutrestore.com or call 1-877-420-6493.

This Patient Information has been approved by the U.S. Food and Drug Administration Revised: DATE