PROTINEX® *Ultra* 5/10

Amino Acid IV Nutrition with Dextrose & Electrolytes

DESCRIPTION

PROTINEX® *Ultra* 5/10 is sterile, hypertonic and non-pyrogenic solution of amino acids, electrolytes & dextrose. When amino acid injections are administered with an appropriate caloric source (e.g., dextrose, fructose, sorbitol), nitrogen balance is improved. Maximal nitrogen utilization is promoted by providing adequate calories to meet metabolic needs, usually at least 168 kJ/kg/day (40 kcal/kg/day).

COMPOSITION

Composition of Amino Acid Chamber (before mixing)

Each 100 ml contains

Active ingredients	**Specification**	**Quantity**
Essential Amino Acids		
L-Isoleucine	USP	0.600 g
L-Leucine	USP	0.730 g
L-Lysine (as Hydrochloride)	USP	0.580 g
L-Methionine	USP	0.400 g
L-Phenylalanine	USP	0.560 g
L-Threonine	USP	0.420 g
L-Tryptophan	USP	0.180 g
L-Valine	USP	0.580 g
L-Histidine	USP	0.480 g
Non-Essential Amino Acids		
L-Arginine	USP	1.150 g
L-Alanine	USP	2.070 g
L-Tyrosine	USP	0.040 g
Glycine (Aminoacetic Acid)	USP	1.030 g
L-Proline	USP	0.680 g
L-Serine	USP	0.500 g
Electrolytes (mEq/L)		
Sodium (Na^+)		70.0
Potassium (K^+)		60.0
Acetate (CH_3COO^-)		150.0
Magnesium (Mg^{2+})		10.0
Chloride (Cl^-)		70.0
Phosphate (as HPO_4^{2-})		60.0

Composition of Dextrose Chamber (before mixing)

Each 100 ml contains

Active ingredient	**Specification**	**Quantity**
Carbohydrate		
Anhydrous Glucose (Dextrose)	BP	20.00 g

INDICATIONS

PROTINEX® *Ultra* 5/10 Infusion is indicated as a source of amino acids in a variety of clinical conditions in which the patient cannot absorb sufficient oral nutrition or in which it is inadvisable to use the oral route of nutrition.

DOSAGE AND ADMINISTRATION

The total daily dose of this solution depends on the patient's metabolic requirement and clinical response.

The nitrogen content and caloric values of **PROTINEX® *Ultra* 5/10** Infusion are -

	Nitrogen Content
Amino Acid Chamber (250 ml)	4.2 g

	Energy Content
Dextrose Chamber (250 ml)	710 Kj (170 Kcal)

Recommended dietary allowances of protein range from approximately 0.8 g/Kg of body weight for adults to 2.2 g/Kg for infants. Daily amino acid doses of approximately 1.0 to 1.5 g/Kg of body weight for adults and 2 to 3 g/Kg of body weight for infants with adequate calories are generally sufficient to satisfy protein needs and promote positive nitrogen balance.

In fluid restricted patients (eg. Renal failure), acceptable total daily administration volumes are dependent upon the fluid balance requirements of the patients.

Depending upon the clinical condition of the patient, approximately 3 litres of solution may be administered per 24 hour period. When used post-operatively, the therapy should begin with 1000 ml on the first post-operative day. Thereafter, the dose may be increased to 3000 ml per day.

USE IN PREGNANCY AND LACTATION

Pregnancy: Animal reproduction studies have not been conducted with amino acid injections. It is also not known whether amino acid injections can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Amino acid injections should be given to a pregnant woman only if clearly needed.

SIDE-EFFECTS

The constant risk of sepsis is present during administration of parenteral nutrition solutions. Since contaminated solutions and infusion catheters are potential sources of infection, it is imperative that the preparation of solution and the placement and

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care of catheters be accomplished under controlled aseptic conditions. If fever develops, the solution, its delivery system and the site of the indwelling catheter should be changed.

The prepared amino acid/dextrose admixture should be used immediately. Any storage should be under refrigeration and limited to a brief period of time, preferably less than 24 hours.
The following metabolic complications have been reported:

metabolic acidosis, hypophosphatemia, alkalosis, hyperglycemia and glycosuria, osmotic diuresis and dehydration, rebound hypoglycemia, elevated liver enzymes, hypo and hypervitaminosis, electrolyte imbalances and hyperammonemia.

CONTRAINDICATIONS

- Patients with acute renal failure.
- Patients with severe liver disease or hepatic coma.
- Hypersensitivity to one or more amino acids.
- Inborn errors of amino acid metabolism concerning one or more amino acid components.

WARNINGS AND PRECAUTIONS

Proper administration of this injection requires a knowledge of fluid and electrolyte balance and nutrition as well as clinical expertise in recognition and treatment of the complications which may occur. The IV administration of this solution can lead to fluid or solute overload resulting in hyper or hypoosmolal states. The risk of hypoosmolal states is especially present in conditions associated with ADH secretion and is proportional to the infusion rate.

Administration of amino acid solution to a patient with hepatic insufficiency may result in serum amino acid imbalances, hyperammonemia, stupor and coma. Conservative doses of this injection should be given to patients with known or suspected hepatic dysfunction. Should symptoms of hyperammonemia develop, administration should be discontinued and the patient's clinical status should be reevaluated.

Administration of amino acid solution in the presence of impaired renal function presents special issues associated with retention of electrolytes.

This solution should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination.

With the administration of this injection; hyperglycemia, glycosuria and hyperosmolar syndrome may result. Blood and urine glucose should be monitored on a routine basis in patients receiving this therapy.

Parenteral nutrition mixtures should be withdrawn slowly as sudden cessation in administration of a concentrated dextrose solution may result in rebound hypoglycemia due to continued endogenous insulin production.

Special care must be taken when giving hypertonic dextrose to patients with impaired glucose tolerance such as diabetics or prediabetics and uremic patients.

Handling of gulcose load is also frequently imparied in patients with liver failure.

Caution must be exercised when administering this injection to patients receiving corticosteroids or corticotropin.

PHARMACEUTICAL PRECAUTIONS

Store below 30˚C temperature. Protect from sunlight. Avoid freezing. Keep out of reach of children. The prepared amino acids/dextrose admixture should be administered immediately. If not, it should be stored under refrigeration (2-8˚C) and used within 24 hours.

Do not remove unit from overwrap until ready for use. The overwrap is an oxygen and U.V. barrier. The inner bag maintains the sterility of the product.

PACKAGING

PROTINEX® *Ultra 5/10* Infusion: Non-PVC Double Chamber bag containing 250 ml of 10% Amino Acid with Electrolytes injection in one Chamber and 250 ml of 20% Dextrose injection in another Chamber. After reconstitution 500 ml contains 5% Amino Acid with Electrolytes and 10% Dextrose injection.

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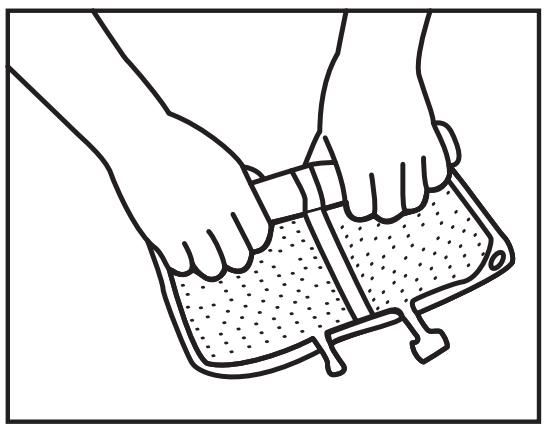
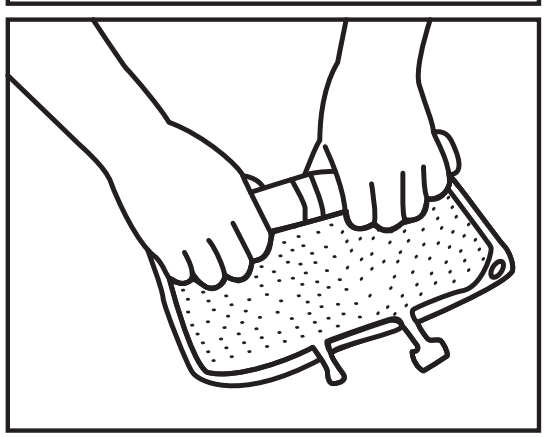
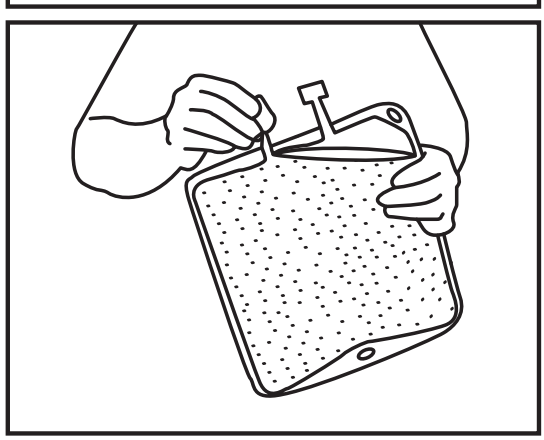
A simple and quick drug product reconstitution system







HOW TO RECONSTITUTE:

1. *Hold the bag at the top (hanging hole end).*

2. *Roll the bag so that maximum liquid is pushed to the bottom of the bag (tube end).*

3. *Press the bag with two fists so that the liquid flows to the tube end.*

The created pressure will break the peelable welding.

পুনর্গঠন প্রণালী:

১. ডাবল চেম্বার ব্যাগটির উপরিভাগটি (ঝুলানোর ছিদ্রযুক্ত প্রান্ত) ধরুন।

২. ব্যাগটি এমনভাবে রোল করুন যেন বেশিরভাগ তরল ব্যাগটির নিম্নভাগে (টিউবযুক্ত প্রান্ত) চলে আসে।

৩. ব্যাগটি দুই হাতের মুঠি দিয়ে চেপে ধরুন যেন তরল অংশ টিউবযুক্ত প্রান্তের দিকে প্রবাহিত হয়।

উৎপন্ন চাপে ডাবল চেম্বার ব্যাগের মাঝের সংযোগস্থলটি খুলে যাবে। এর ফলে অ্যামাইনো এসিড অংশ ও ডেক্সট্রোজ অংশ একত্রে মিলিত হয়ে ইনফিউশনটি পরিপূর্ণভাবে প্রস্তুত হয়ে যাবে।

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