

## ENTERAL NUTRITIONAL COMPOSITION HAVING BALANCED AMINO ACID PROFILE

### BACKGROUND OF THE INVENTION INFORMATION DISCLOSURE

In general, enteral nutrition compositions may be administered orally or by tube feeding. Numerous enteral formulations are utilized in patients with a hyper-metabolic state as effected by burns, trauma, surgery and in patients with malnutrition, chronic illness and in disorders resulting from prolonged periods of reduced oral intake resulting from cerebral vascular accidents or a comatose state.

The enteral compositions have provided benefits and advantages to parenteral nutrition. Elemental diets are often indicated for patients who have a reduced gastrointestinal absorptive surface or exocrine pancreatic insufficiencies. A few of the clinical indications for elemental formulas include: pancreatitis, short gut syndrome, radiation enteritis, GI cutaneous fistulas and Crohn's disease. For some patients, they may also be useful as a transition feeding or even replace total parenteral nutrition (TPN). This recommendation is based on recent clinical findings that demonstrate elemental diets when compared to TPN result in fewer complications, reduced patient length of stay in the ICU and are less expensive. Elemental diets are composed of low molecular weight nutrients and require minimal digestive and absorptive capability. The protein source consists of free amino acids and contains essential and non-essential amino acids. Carbohydrate is typically composed of glucose and hydrolyzed cornstarch (maltodextrin) while the fat content is usually low and primarily consists of essential fatty acids. These diets have minimal residue because of the efficient absorption of the nutrients provided in an elemental form. Most practitioners find that initiating feeding at full strength using low delivery rates is well tolerated, even though elemental formulas are, by nature, hyperosmolar (greater than 300 mOsm/Kg H<sub>2</sub>O). However, in selected cases, initiating feeding with a dilute formula may be preferred. Elemental diets are often administered by needle catheter jejunostomy or endoscopically placed percutaneous jejunal tubes (PEJ) or nasoenteric small bowel feeding tubes in the critically ill patient.

ISOCAL is an enteral formulation by Mead Johnson which utilizes casein and soy for its protein source, glucose oligosacchrides for its carbohydrate source and soy oil and medium chain triglycerides (MCT) oil for its lipid source.

OSMOLITE is manufactured by Ross and utilizes as its protein source casein and soy, corn starch for its carbohydrate source and fifty percent MCT oil, forty percent corn oil and ten percent soy oil for its lipid source.

ENSURE is manufactured by Ross and utilizes casein and soy for protein source, corn starch and sucrose for a carbohydrate source and corn oil for a lipid source.

SUSTACAL manufactured by Mead Johnson utilizes casein and soy for its protein source, corn syrup and sucrose for its carbohydrate source and soy oil for its lipid source.

ENSURE PLUS manufactured by Ross is a high protein, high calorie composition using soy and casein for its protein source, corn starch and glucose for its carbohydrate source and corn oil for its lipid source.

MAGNACAL manufactured by Sherwood Medical is a high density composition with 2.0 calories/ml. MAGNACAL utilizes casein for its protein source, corn syrup for its carbohydrate source and soy oil for its lipid source.

TRAUMACAL manufactured by Mead Johnson utilizes casein for its protein source, corn syrup and sucrose for its carbohydrate source and 70 percent soy bean oil and 30 percent MCT oil for its lipid source.

ISOTEIN HN is manufactured by Sandoz and utilizes lactalbumin for its protein source, maltodextrin for its carbohydrate source and soy oil and MCT oil for its lipid source.

VIVONEX T.E.N. is manufactured by Sandoz and comprises branched chain amino acids, glutamine and arginine as the protein source, safflower oil as the lipid source, and maltodextrin and modified starch as the carbohydrate source.

IMPACT is manufactured by Sandoz and comprises arginine and caseinates as the protein source, maltodextrins as the carbohydrate, and menhaden oil and structured lipids as the lipids source.

U.S. Pat. No. 4,752,618 describes a dietary supplement and method of minimizing infections therewith, comprising omega-3 and omega-6 fatty acid such as safflower oil and menhaden oil.

U.S. Pat. No. 4,847,296 describes triglyceride preparations for enteral administration to prevent catabolism and increase protein synthesis in subjects undergoing severe metabolic stress.

U.S. Pat. No. 5,053,387 describes enteral compositions for treating traumatic injury comprising an intact protein (from lactalbumin egg albumen or whey and the like), arginine, carbohydrate (glucose polymers, disaccharides, starches and the like), lipid comprising omega-3 fatty acids of fish oil, and necessary vitamins and minerals.

U.S. Pat. No. 5,231,085 describes enteral compositions comprising arginine, ornithine, a nucleobase, omega-3 polyunsaturated fatty acids, and omega-6 polyunsaturated fatty acids.

Other background references on enteral feeding compositions and methods include:

Alexander, J. W., MacMillan, B. G., Stinnett, J. P. et al: Beneficial effects of aggressive protein feeding in severely burned children. *Ann. Surg.* 192:505-517, 1980;

Dominioni, L., Trocki, O., Mochizuke, H., et al: Prevention of severe postburn hypermetabolism and catabolism by immediate intragastric feeding. *J. Burn Care Rehab.* 5:106-112, 1984;

Bower, R. H., Muggia-Sullam, M., Vallgren, S., et al: Branched chain amino acid enriched solutions in the septic patient. A randomized. prospective trial. *Ann. Surg.* 203:13-20, 1986;

Cerra, F. G., Siegal, J. H., Coleman, B., et al: Septic autocannibalism: A failure of exogenous nutritional support. *Ann. Surg.* 192:570-580, 1980;

Cerra, F. B., Upson, D., Angelico, R., et al: Branched chains support post-operative protein synthesis. *Surgery* 92:192-198, 1982;

Cerra, F. B. Shronts, E. P., Konstantinides, N. N., et al: Enteral feeding in sepsis: A prospective randomized, double-blind trial. *Surgery* 98:632-638, 1985;

Law, D. K., Durdick, S. J. and abdon, N. I.: The effect of dietary protein depletion on immuno competence: the importance of nutritional repletion