

12 CLINICAL PHARMACOLOGY

12.3 Pharmacokinetics

Absorption

Systemic absorption of SBI (10 g) was evaluated in 12 healthy adult subjects who consumed pudding containing SBI versus pudding alone. No absorbed, intact immunoglobulin was detected in plasma. Overall area under the curve (AUC) for leucine in the SBI group was significantly higher ($p < 0.05$) compared to the non-SBI group. Some SBI may have been digested in the GI tract leading to heightened leucine levels especially at 60 to 120 minutes after administration. Plasma amino acids had returned to fasting levels by 90 minutes after pudding alone, but remained above baseline levels until 120 to 150 minutes after SBI-containing pudding was administered. There is no metabolism in hepatic or renal organs.

Food Effect

ENTERAGAM has been fed alone and in combination with a variety of foods. There are no food effects on the activity of ENTERAGAM.

Distribution

ENTERAGAM has only been detected in the GI tract.

Metabolism and Elimination

Between 20-25% of orally-administered immunoglobulins have been shown to survive initial digestive processes in the stomach, providing nutritional management of GI function and morphology. Transit time from oral ingestion of bovine immunoglobulins occurs between 6 and 40 hours depending on the health of the individual. In infants with diarrhea, approximately 5-12% of orally-administered immunoglobulins were excreted in feces. Immunoanalysis of feces from healthy adults, however, found that only minute amounts ($< 0.01\%$) of orally-administered immunoglobulins were eliminated through the GI tract. Differences in survival through the GI tract may be due to variation in transit time because of co-administration with proton pump inhibitors, gastrointestinal infection, hydration state or disease resulting in diarrhea.

Special Populations

There have been no transit time studies of orally-delivered immunoglobulins in geriatric patients. Several studies in infants have been performed demonstrating that immunoglobulin transit times through the GI tract of infants occur between 6 and 72 hours after ingestion.