

1 INDICATIONS AND USAGE

1.3 Clinical dietary management of HIV-associated enteropathy including chronic loose or frequent stools

ENTERAGAM is indicated for the clinical dietary management of human immunodeficiency virus (HIV) – associated enteropathy in infected patients who have chronic loose or frequent stools. Infection by HIV is thought to adversely affect the intestinal barrier and gut-associated lymphoid tissue (GALT). HIV-associated enteropathy is distinguished from other enteropathies by persistent, well-established diarrhea for greater than a month in duration without an associated bacterial infection. ENTERAGAM has been shown clinically to decrease stool frequency, improve stool consistency and manage GI symptoms (*e.g.*, cramping, urgency, incontinence, and nocturnal stools).

Regardless of indication, ENTERAGAM, as an FDA-regulated medical food, must be used under medical supervision. ENTERAGAM is dispensed by prescription (Rx).