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2. EnteraGam

# EnteraGam

**Generic name:** [serum-derived bovine immunoglobulin/protein isolate](#)

**Company:** Entera Health, Inc.

Medically reviewed by [Sophia Entringer, PharmD](#). Last updated on Aug 23, 2023.

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**Treatment for:** *Dietary Management of Enteropathy*

## Overview

EnteraGam (serum-derived bovine immunoglobulin/protein isolate, SBI) is a medical food product indicated for the clinical dietary management of enteropathy (bowel problems) to be used under a doctor's medical supervision. It is given orally as a powder mixed into a liquid.

EnteraGam is indicated for:

- use in patients for the clinical dietary management of enteropathy in patients who have a limited or impaired capacity to ingest, digest, absorb, or metabolize certain nutrients.
- the clinical dietary management of enteropathy in patients with chronic loose or frequent stools (for example, diarrhea-predominant [irritable bowel syndrome](#) [IBS-D], inflammatory bowel disease [IBDD] and [HIV](#)-associated enteropathy).

Utilization of nutrition depends on appropriate digestion of food and optimal gut metabolism and absorption of nutrients. Some patients (for example, those with IBS-D or HIV-associated enteropathy) are not able to adequately ingest, digest, absorb, or metabolize food and certain nutrients, including water. Medical foods are meant to manage conditions or diseases in which there is a distinct nutritional need. EnteraGam is a 'generally recognized as safe' (GRAS) ingredient for enteral and/or oral administration, as designated by the FDA.

EnteraGam is labeled for use in adults and children two years of age and older. EnteraGam is **contraindicated** (not to be used) in patients with a hypersensitivity (allergy) to beef or any other components in the product. The active ingredient in the product is a beef-derived protein that consists of more than 50 percent immunoglobulin.

EnteraGam is manufactured and distributed by Entera Health, Inc. and has been commercially available since August 2013.

**EnteraGam Formulations Available in the U.S.**

Generic Name	Brand Name	FDA-Approved Uses	Medical Food Formulation
Serum-derived bovine immunoglobulin/protein isolate (SBI)	EnteraGam by Entera Health	Clinical dietary management of an intestinal disorder known as enteropathy (e.g., in diarrhea-predominant irritable bowel syndrome (IBS-D) and HIV-associated enteropathy); help manage chronic diarrhea and loose stools.	Active ingredient: 5 grams of SBI per packet. Inactive ingredients: 5 grams dextrose, trace amounts of sunflower lecithin. EnteraGam does not contain any milk products (lactose, casein, whey), is gluten-free, dye-free, and soy-free.

## What is a Medical Food?

Medical foods are regulated by the FDA under the Orphan Drug Act, and are specially formulated to be taken by mouth or given directly into the gastrointestinal tract (as through a tube). Medical foods are to be used under a physician's care but are not "prescription only" products as defined by the FDA. Medical foods are part of ongoing care to ensure adequate nutritional needs are met in those who cannot achieve adequate nutrition by normal dietary intake. Ingredients in medical foods must be generally recognized as safe (GRAS) by the FDA.

According to the [FDA](#), medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. For example, medical foods do not have to undergo premarket review or approval. Medical foods must comply with all applicable FDA requirements for foods, including the Current Good Manufacturing Practice regulations. FDA does not maintain a list of medical food products.

## EnteraGam Dosing

Drug	Dose: Adult	Dose: Children 2 years and older
Serum-derived bovine immunoglobulin/protein isolate (SBI)	Initially, one packet daily, which may be increased up to 4 packets per day as directed by your doctor. Stir one packet into at least 4 ounces of water or other liquid (not hot); do not shake. Take each dose immediately after mixing. Do not store mixed product. May also mix into yogurt or pudding instead of liquid. May divide into two doses to be taken once in the morning and once in the evening as directed by your doctor.	Children 2 years and older can be administered one half (1/2) packet of EnteraGam once daily or in divided doses in liquids or food according to the doctor's instructions.

EnteraGam has been safely used in various clinical studies up to 1 year in length among adults and children and has no restrictions on the length of therapy.

If you have additional questions about EnteraGam, you can ask your healthcare provider for a package insert that is written for healthcare providers.

## Before receiving EnteraGam

Before you receive EnteraGam, tell your healthcare professional about all of your medical conditions. This includes:

- if you are allergic to beef or beef-products.
- if you are pregnant or plan to become pregnant. Your doctor will decide if the benefit of EnteraGam for you outweighs any risk to your baby.
- if you are breastfeeding or plan to breastfeed. Your doctor will decide if the benefit of EnteraGam for you outweighs

any risk to your baby.

## EnteraGam Side Effects

EnteraGam common side effects include:

- mild nausea
- constipation
- flatulence
- stomach cramps
- headache
- increased urination

These side effects were reported in 2 to 5 of every 100 patients (2 to 5% incidence). To date, serious side effects with EnteraGam have not been reported in clinical trials.

EnteraGam has not been studied in pregnant or nursing women.

Call your doctor for medical advice about side effects. You can report side effects to FDA by calling 1-800-FDA-1088.

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# EnteraGam Drug Interactions

No significant interactions have been observed between EnteraGam and other commonly prescribed medications. In addition, no specific food effects on the activity of EnteraGam have been noted.

Enteragam has only been detected in the gastrointestinal tract, and is not absorbed into the blood stream.

## Does EnteraGam interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

EnteraGam

+

Enter a drug name

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## Who should not receive EnteraGam?

The active ingredient in EnteraGam is a beef-derived protein. This medical food should not be given if you are allergic to beef or have had a severe allergic reaction to any other active or inactive ingredient. If you experience shortness of breath, immediately discontinue the product and contact your healthcare provider.

## What are the ingredients?

**Active ingredient:** serum-derived bovine immunoglobulin/protein isolate, SBI

**Inactive ingredients:** dextrose; sunflower lecithin

Read more: [Inactive ingredients](#)

## More about EnteraGam (immune globulin oral)

- [Reviews \(22\)](#)

## Related treatment guides

- [Irritable Bowel Syndrome with Diarrhea](#)

## Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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