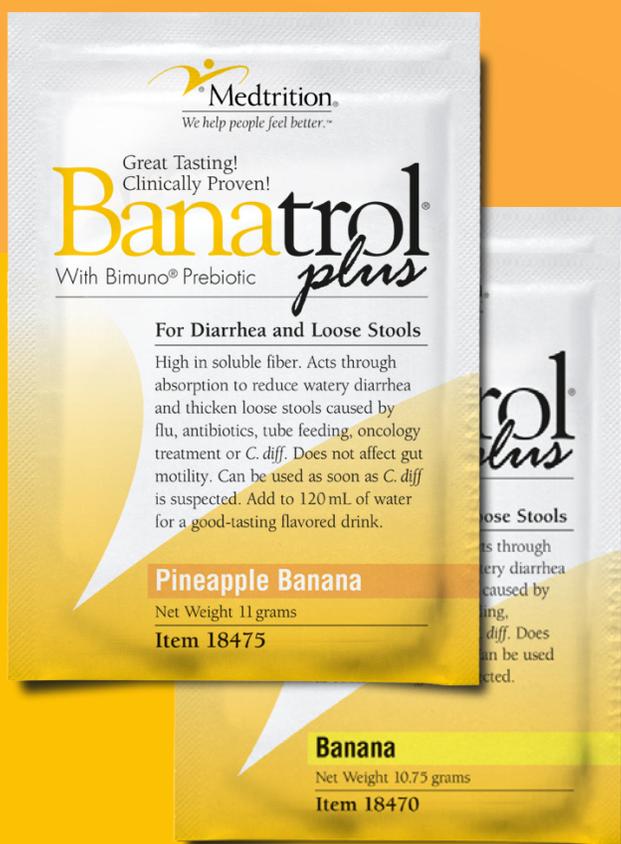


# Banatrol® Plus

For diarrhea and loose stools



- C. Difficile and Infectious disease
- Antibiotics and Medications
- Gastroenteritis, Enterocolitis
- Oncology treatments
- Enteral tube-feeding intolerance

Clinically proven to improve outcomes, control costs, and reduce demands on staff.

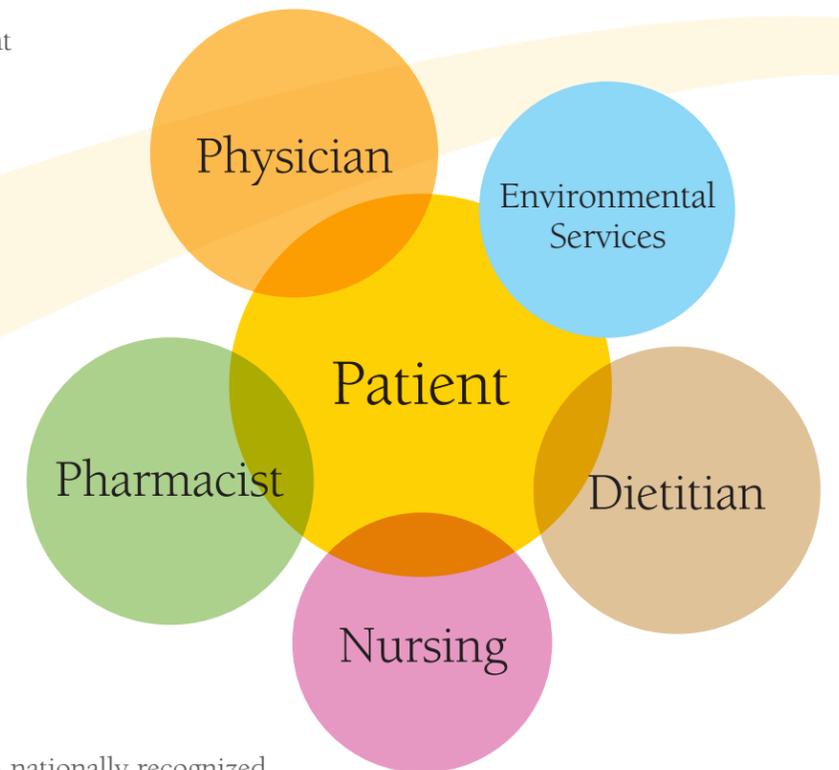


**D**iarrhea impacts the entire facility and typically requires a multidisciplinary approach involving the clinical dietitian, nursing, the physician, pharmacy, and Environmental Services.

**The costs of diarrhea to the individual and the facility are both extensive and expensive:**

- Personal discomfort and embarrassment
- Risk of spread of *C. diff*
- Increased use of devices, barriers
- Loss of skin integrity
- Increased need for medications
- Dehydration
- Malnutrition / Reduced intake
- Increased risk of UTI
- Increased demands on staff

*Let's make everyone happy!*



**Medtrition delivers . . .**

Made to exacting standards, certified by a nationally recognized independent laboratory, and manufactured under Good Manufacturing Practices (GMP) certified by the Pennsylvania Department of Agriculture, our products meet the needs of the patient . . . and the entire healthcare team.

**A Global supplier**

Medtrition is a global supplier of medical food products that effectively address challenging medical conditions dealt with on a daily basis.

Our range of products includes the leading worldwide brand of concentrated liquid proteins; the leading range of medicals foods for wound care; and innovative products for bowel management and urinary tract infections. Our specialty products include offerings for both renal and hepatic disease.

Our products are used by leading hospitals and long-term-care facilities across the globe. We invite you to visit our primary website, [www.medtrition.com](http://www.medtrition.com), and the in-country websites of our international distributors.

## A safe, cost-effective, clinically proven treatment for diarrhea

Banatrol® Plus significantly reduces the severity and length of time patients suffer from diarrhea. Banatrol Plus is high in pectin from banana flakes, a soluble fiber that acts through absorption to reduce watery diarrhea and promote normalization of the colon's fluid composition. Soluble fiber is gel-like and helps thicken stool consistency but does not promote hard stools and does not slow gut motility. Banatrol Plus also contains a prebiotic that enhances the beneficial bacteria population. Banatrol Plus may be initiated at the first sign of diarrhea or given prophylactically when administered medications are known to cause diarrhea.

Banatrol Plus treats diarrhea and loose stools associated with the following:

- C. Difficile and Infectious disease
- Antibiotics and Medications
- Gastroenteritis, Enterocolitis
- Oncology treatments
- Enteral tube-feedings

## Two products for every application

- Unsweetened Banana-flavored Banatrol Plus for oral and tube-feed use
- Sweetened Pineapple Banana Banatrol Plus drink mix for oral use

### Banatrol Plus contains:

- Banana flakes to solidify the stool.
- Bimuno prebiotic to support beneficial bacteria in the gut.

Banatrol Plus is a medical food and not a medicine.

Banatrol Plus generally starts to thicken the stool within two to three days, but can take up to five to seven days depending on the severity of the diarrhea, the individual's response, and a number of contributing factors, such as tube feeding intolerance, use of diarrhea-causing antibiotics, the presence of bowel disease, sorbitol-containing medications and malnutrition.

## Banana Flakes

Bananas have long been used as part of a BRAT Diet (bananas, rice, applesauce, and toast) for the treatment of diarrhea. Banatrol Plus incorporates key aspects of the BRAT diet in a convenient packet!

Bananas possess a unique food quality: they contain equal amounts of sugar and fructose, making them a low FODMAP (Fermentable, Oligo-, Di-, Mono-saccharides and Polyols) food. Bananas are rich in amylase-resistant soluble fiber and potassium. The amylase-resistant starch is acted on by the gut bacteria and results in the production of short-chain fatty acids. The presence of short-chain fatty acids in the colon stimulates the absorption of water and electrolytes by the colonocytes, helping to form firmer stools.

Banatrol Plus is non-constipating, does not create hard stools, and does not slow gut motility.

## Banatrol Plus ends the diarrhea-constipation cycle of antidiarrheal medications!

### Loose Stools

In addition to addressing diarrhea, Banatrol Plus is very effective in resolving loose stools, which can be as incapacitating as diarrhea to residents in long-term care. One or two packets of Banatrol Plus will solidify the

stool, reducing urgency and accidental bowel movement. It is non-constipating and can be used long term without side effects.

## Clinical Study: Banana flakes are shown to control diarrhea in enterally fed patients, even those with C. diff!

In a published study, thirty-one patients with diarrhea and receiving enteral feedings were randomized to receive either banana flakes or medical treatment for diarrhea. At the conclusion of the study, the banana-flakes group had less diarrhea clinically, with 57% of the subjects diarrhea free on their last study day as opposed to 24% of the medically treated subjects. *This occurred despite a threefold increase in the number of patients testing positive for Clostridium difficile toxin in the banana flake group.* Banana flakes can be given concurrently with a workup for C. difficile colitis, thereby expediting treatment of diarrhea.<sup>1</sup>

<sup>1</sup> *Nutrition in Clinical Practice*, Vol. 12 No. 2, April 1997. "Banana Flakes Control Diarrhea in Enterally Fed Patients." Elizabeth A. Emery, MS, RD, CNSD, Syed Ahmad, MD.

## Bimuno prebiotic replenishes beneficial bacteria

Each packet of Banatrol Plus contains 2.75 grams of Bimuno, a prebiotic transgalactooligosaccharide, which is a *food source* for the beneficial bacteria that reside in the gut or colon. Unlike *probiotics*, prebiotics are not live bacteria/fungal spores so they are not destroyed or digested in the stomach or intestine or destroyed by antibiotics. Clinical studies show that Bimuno promotes growth of just the beneficial bacteria, which then proliferate at a much faster rate than harmful bacteria, helping to restore normal gut flora.<sup>1</sup>

## What is Bimuno?

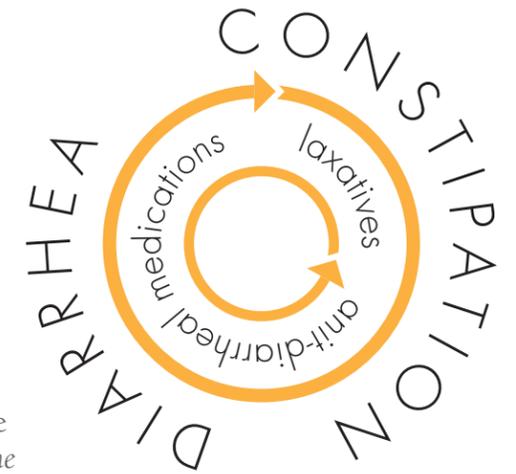
Bimuno is the resulting product of intensive research and development, including peer-reviewed clinical studies conducted in collaboration with the University of Reading's Food Microbial Sciences Unit and other globally recognized research institutes. Bimuno works naturally with the body to maintain and/or restore a healthy balance of bacteria within the GI tract that is lost because of aging, infection, laxatives, antibiotics, inadequate food intake, chemotherapy, and radiation therapy.

Bimuno is classed as the only second-generation (B-GOS) prebiotic. This is because it offers added functionality beyond its prebiotic (increases and strengthens beneficial bacteria) and bifidogenic (increases and strengthens immunity-boosting bacteria) effects. Bimuno is a unique patented prebiotic with multifaceted benefits.

## How Bimuno works

1. Bimuno reaches the small intestine intact.
2. In the small intestine, it inhibits adhesion of GI-pathogenic bacteria.
3. In the large intestine, it is fermented by the specific beneficial bacteria (bifidobacteria). This leads to a change in pH balance, resulting in a positive change in the microflora.
4. This selective fermentation increases and strengthens the immunity-boosting bifidobacteria.
5. The resulting increased NK cell and phagocytic activity produces a direct positive effect on the innate immune system.<sup>2</sup>
6. An increase in anti-inflammatory cytokines and decrease in pro-inflammatory cytokines produce a positive effect on the adaptive immune system.<sup>3</sup>

The advantage of Bimuno is its ability to enhance the growth of only the good bacteria. Other prebiotics can be used as an energy source by both good and bad gut bacteria. Bimuno's chemical structure is designed similar to a lock and key that match the shape of the good gut bacteria so only they can digest it.



Bimuno prebiotic is shown in clinical studies to enhance good bacteria in the GI tract. Research published in the *American Journal of Clinical Nutrition* shows that the prebiotic supplement Bimuno significantly increases levels of bifidobacteria in humans within seven days.<sup>2</sup> Bifidobacteria are the most important types of positive, or “good,” bacteria in the gut, as they specifically stimulate the immune system, increase resistance to infection and diarrheal disease, reduce markers of chronic gut problems, and enhance overall gut health.<sup>3</sup>

2 Depeint F, Tzortzis G, Vulevic J, l'Anson K & Gibson GR. “Prebiotic evaluation of a novel galacto-oligosaccharide mixture produced by the enzymatic activity of *Bifidobacterium bifidum* NCIMB 41171 in healthy humans: a randomized, double-blind, cross-over, placebo-controlled intervention study.” *American Journal of Clinical Nutrition*, March 2008.

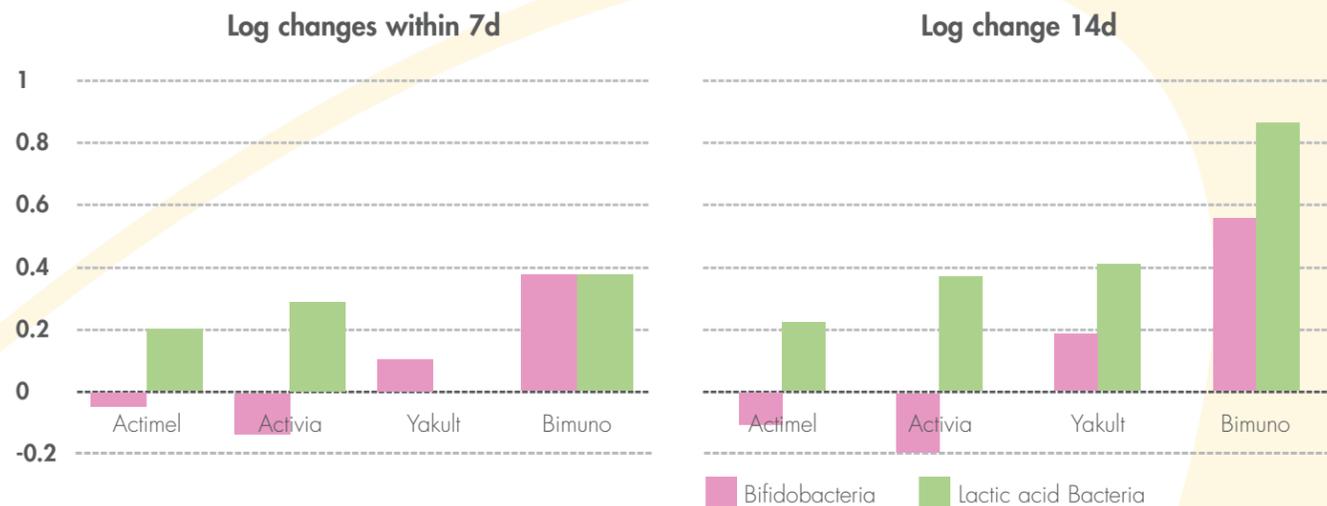
3 Macfarlane GT, Steed H, Macfarlane S. “Bacterial metabolism and health-related effects of galacto-oligosaccharides and other prebiotics.” *Journal of Applied Microbiology*, 2008; 104: 305-344.

## Bimuno versus probiotic from commercially available probiotics

**Study:** effect of commercially available probiotic and prebiotic foods on the composition of the colonic microflora.

- A double-blind, randomized, single-center, parallel design study in healthy adult (20–59 years old) individuals looking at the effect of commercially available probiotic products (Actimel, Activia, Yakult) and Bimuno on the composition of the colonic microflora.

## Bimuno Prebiotic versus Probiotic



**The only significant change** in the numbers of colonic beneficial bacteria was recorded after the consumption of the prebiotic product (Bimuno) that resulted in significant increase of:

- the *Bifidobacterium* spp population after 7 and 14d
- the *Lactobacillus* spp population after 14d

Tzortzis et al., *J Nutr* 2005; Depeint et al., *Am J Clin Nutr* 2008

## Dosing and Administration

Banatrol Plus can be administered by mouth, G-tube, or J-tube.

### Oral

**Diarrhea:** One packet of Banatrol Plus TID (three times daily). Titrate the dose as needed with a minimum of one packet/day and maximum of six packets/day. Continue until diarrhea is resolved.

**Loose Stools:** One packet once or twice a day as needed. Banana-flavored Banatrol Plus is unsweetened and typically added to a moist food or beverage for oral use. Stir one packet into 120 mL of water or fruit juice, or moist foods such as applesauce, yogurt, pudding and oatmeal.

Pineapple Banana–flavored Banatrol Plus is sweetened and can be mixed directly into 120 mL of water for a good-tasting flavored drink.

## Tube Feeding

One packet of Banatrol Plus TID every six to eight hours of feeding. Add 120 mL of room-temperature water to a 240-mL cup. Slowly stir in the contents of one packet of Banatrol Plus. Stir until dissolved. Administer slowly via syringe down tube. Depending on the size of the feeding tube, you may need to use the syringe plunger to gently push mixture down the tube. Flush with 30 ml water before and after administration. Do not mix with tube feeding.

When administering Banatrol Plus via feeding tube, we recommend a size-14 French feeding tube or larger to reduce the risk of clogging the tube. **Use a minimum of 120 mL water to mix the product. Slowly stir one packet of Banatrol Plus into 120 mL of water. Mix thoroughly.** Infuse via syringe down feeding tube.

### Smaller tubes (FRENCH):

Administer each pack of Banatrol Plus in two divided boluses. For small tubes, slowly stir a half-packet of Banatrol Plus into 120 mL water. Mix thoroughly. Infuse via syringe down feeding tube. Flush with 30 mL water and repeat the procedure to administer the second half of the packet.

Some patients with J-tubes may not tolerate the volume of fluid used in the divided-bolus method noted above. In these cases, frequent small doses separated by at least one to two hours maybe better tolerated; i.e., each half-packet of Banatrol Plus mixed with 120 mL of water bolus should be separated by at least one to two hours.

## Ostomies (Ileostomy and Colostomy)

Banatrol Plus can help thicken stools for individuals with an ostomy. Adherence to an ostomy diet is required to achieve good results. The healthcare clinician will need to determine the regimen of Banatrol Plus that works for the patient. In general, those with colostomies require the same dose of Banatrol Plus as those without a colostomy. Patients with ileostomies generally require a higher total amount of Banatrol Plus, given in small frequent doses.

**Colostomy with loose stools:** Start with one packet of Banatrol Plus twice a day, wait three to five days, and adjust dose based on the stool consistency: decrease to one packet for firm stools, or increase to one packet three times a day if needed. Allow at least three days for Banatrol Plus to take effect before increasing the dose. Over time, the stool from a colostomy starts to “normalize”; many colostomy patients are able to decrease the Banatrol Plus to just one packet a day, one packet every other day, or even none, depending on their diet and other contributing conditions.

**Ileostomy with loose/liquid stools:** Start with half-packet of Banatrol Plus before and after meals and before bed, wait three to five days, and adjust dose based on stool consistency—often patients are able to determine what works for them. Common regimens that patients have used with good results (thick/less watery stools) include: one packet Banatrol Plus one hour before meals and bed, one hour after meals and at bed, or one to two packets every three to four hours while awake.

## Drug Interaction

Banatrol Plus does not interact with any medications and works best when given at the start of loose stools.

## Immuno-compromised patients

Banatrol Plus is safe for immune-compromised patients since the prebiotic in Banatrol Plus is food for the beneficial bacteria in the gut rather than the live bacteria/fungal spores found in a probiotic.

## Allergens:

People who have a latex allergy also may have a risk of being allergic to fruits such as bananas, avocados, passionfruit, plums, strawberries, and tomatoes. This is known as latex-fruit syndrome, which can result in hives, sneezing, coughing, and itching and can also lead to anaphylactic reaction.

## Lactose

The prebiotic in Banatrol Plus is galactooligosaccharide (B-GOS), which is produced by the enzymatic conversion of lactose. During this process, a small inconsequential amount of lactose (0.72 g per packet) remains intact, similar to the production of Lactaid milk.

## Antibiotic use

For antibiotics that are known to cause diarrhea (such as Clindamycin®, Fluoroquinolones (Levaquin®, Cipro®), Cephalosporins, Sulfonamides, extended-coverage Penicillins), Banatrol Plus can be used prophylactically at the start of antibiotic therapy and continued for the duration of therapy.

## For *C. diff* infection (CDI)

Banatrol Plus augments antibiotic therapy and does not inhibit gut motility. Banatrol Plus acts to thicken the stool and helps to reduce the bacteria load with stool elimination.

Unlike anti-diarrheal medications, Banatrol Plus can be started immediately while awaiting stool test results for suspected *C. diff* infection.

**Banatrol Plus contains the same amount of potassium as 1/4 of a banana.**

## Specifications:

Kcal/mL ..... 0.33  
When mixed in 120 mL of water

**Caloric Distribution** (% of kcal)  
Protein ..... 0%  
Carbohydrate ..... 100%  
Fat ..... 0%

### Soluble Fiber Source:

Natural banana flakes

### Prebiotic Source:

Transgalactooligosaccharide

**Osmolality:** 240 mOsm/kg water  
When mixed in 120 mL of water

HCPCS Code: B4104

Product	Unit	Potassium mg	High Potassium Foods for Comparison (per cup or as noted)			
Banatrol® Plus	Pack	120 mg (3.1 mEq)	Potatoes	740 mg	OJ	390 mg
Potassium Supplements for Comparison			Dried Fruit	700 mg/1/2 c	Banana small	390 mg
Klor-Con	Tablet	312 mg	Beans (dried)	585 mg	Broccoli	312 mg
Klor-Con	Tablet	390 mg	Prune Juice	500 mg	Bran Cereal	312 mg
Klor-Con	Tablet	780 mg	Greens	500 mg	Asparagus	312 mg
K-Dur Tablets	Tablet	780 mg	Tomatoes	500 mg/each	Beets	273 mg
KCI Liquid	15 mL	780 mg	Melon	273 mg		
KCI Liquid	15 mL	1560 mg				

## Ingredients:

**Banana Flavor (unsweetened):** Banana Flakes, Bimuno (transgalactooligosaccharide, lactose, glucose, gum acacia, galactose).

**Pineapple Banana Flavor (sweetened):** Banana Flakes, Bimuno (transgalactooligosaccharide, lactose, glucose, gum acacia, galactose), Pineapple Banana and Natural Flavors, Guar Gum, Sucralose, Beta-carotene, Salt.

Gluten and Fat Free

**Our no-risk guarantee.** We stand behind our products. Try any one of our products and if after 60 days you are not completely satisfied, we will refund 100% of the purchase price.

**MAR and PYXIS systems.** All products are bar-coded for dispensing through MAR & PYXIS systems.

**In-servicing:** Available to clinical nutrition, nutrition support teams, critical care teams, nursing staff including educators and trainers, and physicians.

Item Number	Case UPC	Billing Code	Packaging
18470 Banana	5-07-94688-18470-5	94688-0184-70	75/10.75 g packets
18475 Pineapple Banana	5-07-94688-18475-0	94688-0184-75	75/11 g packets



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