



# InterFase<sup>®</sup> and InterFase<sup>®</sup> Plus

Gastrointestinal antibiofilm enzyme formulation with and without disodium EDTA



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## Gastrointestinal antibiofilm enzyme formulation with and without disodium EDTA

### Breaking through the biofilm matrix

InterFase® is a highly specialized enzyme formula that supports normal gastrointestinal function and microbiota by assisting enzymatic degradation of biofilm communities of bacteria and yeast allowing for repopulation with salutary species.

While digestive enzymes are taken with meals to help digest food, the enzymes in InterFase® are taken between meals to help degrade bacterial and yeast biofilm communities, a complex aggregation of microorganisms embedded in a protective extracellular, polymeric matrix. Biofilms make it enormously difficult to shift the balance of microbiota. InterFase® has documented ability to lyse polysaccharides making up biofilm matrices as well as degrade bacterial and yeast cell wall structures. This innovative enzyme formulation provides a synergistic combination of glucoamylase, cellulase, hemicellulase/pectinase, beta-glucanase, protease/peptidase complex with dipeptidyl peptidase-IV (DPP-IV) activity, lysozyme, chitosanase, and Serratia peptidase that targets and disrupts GI bacteria and yeast biofilms.

For enhanced antibiofilm activity, InterFase® Plus combines the enzymes in InterFase® with disodium ethylenediaminetetraacetic acid (EDTA), a compound that binds the metals needed for biofilm formation.



*InterFase® is a unique enzyme formulation especially designed to disrupt gastrointestinal bacterial and yeast biofilm communities. Enzymes in InterFase® are selected for their ability to lyse the extracellular polymers commonly found in biofilm as well as degrade bacterial and yeast cell wall structures. The lytic effect of InterFase® on biofilm has been documented using the well-established MBEC™ P&G assay for antibiofilm activity. InterFase® Plus includes ethylenediaminetetraacetic acid (EDTA) which binds the metals needed for biofilm formation.*

### INTERFASE®

#### Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	
Proprietary Enzyme Blend <sup>†</sup>	425 mg*
Providing the following active enzymes:	
<b>Polysaccharide Specific Enzymes</b>	
Glucoamylase (with isomaltase side chain activity)	
Chitosanase	
Cellulase	
Hemicellulase (xylanase) and Pectinase Complex	
Beta-Glucanase	
<b>Protein and Peptide Specific Enzymes</b>	
Protease/Peptidase Complex with endopeptidase, exopeptidase, and DPP-IV activity	
<b>Other Enzymes</b>	
Lysozyme (from egg white)	
Serratia peptidase (enteric-coated) <sup>‡‡</sup>	

\*Daily Value not established.

Other ingredients: Vegetarian capsule (hydroxypropyl methylcellulose, water), coconut oil powder, and microcrystalline cellulose.

<sup>†</sup>Patent Pending, ProThera®, Inc.

<sup>‡‡</sup>Peptizyme SP®, a registered trademark of Specialty Enzymes.

**Caution:** If you are pregnant, nursing, have a medical condition, taking prescription drugs, or are allergic to eggs, consult your healthcare professional before using this product. Keep out of reach of children.

**K-INT 60 vegetarian capsules**

**K-INT-12 120 vegetarian capsules**

### Suggested use

Depending on age and size, 1 capsule, 1 to 4 times daily between meals or as directed by a healthcare professional. The capsules should be taken away from meals to maximize the enzyme effects.

### INTERFASE® PLUS

#### Supplement Facts

Serving Size 2 Capsules

Amount Per 2 Capsules	
Proprietary Enzyme <sup>†</sup> / EDTA Blend	675 mg*
Providing the following active enzymes:	
<b>Polysaccharide Specific Enzymes</b>	
Glucoamylase (with isomaltase side chain activity)	
Chitosanase	
Cellulase	
Hemicellulase/Pectinase Complex	
Beta-Glucanase	
<b>Protein and Peptide Specific Enzymes</b>	
Protease/Peptidase Complex with endopeptidase, exopeptidase, and DPP-IV activity	
<b>Other Enzymes and EDTA</b>	
Lysozyme (from egg white)	
Serratia peptidase (enteric-coated) <sup>‡‡</sup>	
EDTA (as disodium EDTA)	

\*Daily Value not established.

Other ingredients: Vegetarian capsule (hydroxypropyl methylcellulose, water), coconut oil powder, and microcrystalline cellulose.

<sup>†</sup>Patent Pending, ProThera®, Inc.

<sup>‡‡</sup>Peptizyme SP®, a registered trademark of Specialty Enzymes.

**Caution:** This product is not intended for long-term daily use. Do not use this product if you are pregnant or nursing, have kidney or liver condition or are below the age of 18. If you have any other medical condition, if you are taking prescription drugs or allergic to eggs, consult your healthcare professional before using this product. Keep out of reach of children.

**K-INTP60 60 vegetarian capsules**

**K-INTP120 120 vegetarian capsules**

### Suggested use

Depending on age and size, 2 capsules, 1 to 4 times daily between meals or as directed by a healthcare professional. The capsules should be taken away from meals to maximize the enzyme effects.

<sup>†</sup>These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.

# Specialized Enzymes Degrade Bacterial and Yeast Biofilm Communities

## Documented antibiofilm activities

InterFase® and InterFase® Plus were developed using in vitro testing of antibiofilm activity. The MBEC™ P&G assay for antibiofilm activity was developed by the Biofilm Research Group at the University of Calgary, which is staffed by some of the world's leading authorities on biofilm microbiology. The MBEC™ device consists of multiple wells and pegs on which biofilm can be reproducibly formed and the impact of new compounds or formulations may be assessed. Antibiofilm activity is assessed by minimum biofilm eradication concentration (MBEC™) values which are determined by reductions in turbidity measured by optical density at 630 nm.

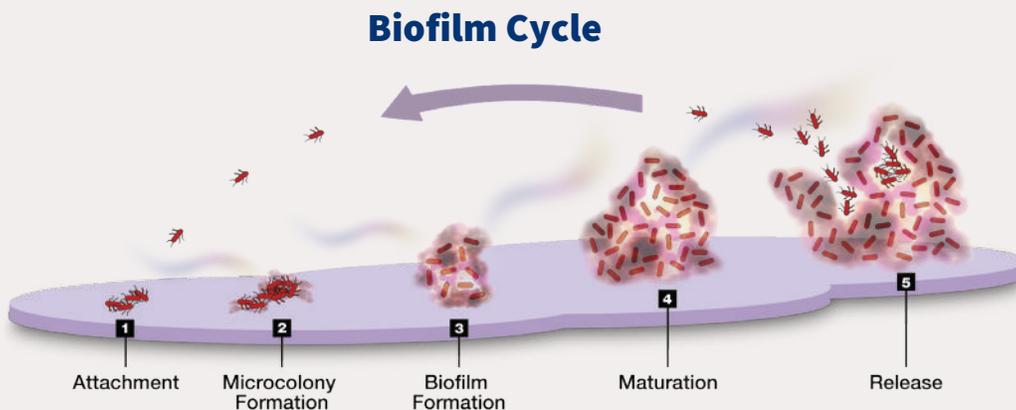
InterFase® and InterFase® Plus were found to have significant antibiofilm activity resulting in meaningful degradation of biofilm communities of Gram negative and Gram positive bacteria and yeast. In general, InterFase® Plus containing EDTA demonstrated significantly greater antibiofilm activity than did InterFase®. InterFase® and InterFase® Plus have no adverse effects on healthful biofilm formed by *Bifidobacterium bifidum* PT131, *Bifidobacterium breve* PT132, *Bifidobacterium longum* PT136, *Lactobacillus casei* PT116, *Lactobacillus rhamnosus* PT112, and *Lactobacillus salivarius* ATCC 29602.

## Protects against tissue irritation and supports healthy inflammation metabolism

InterFase® supplies significant amounts of Serratia peptidase, a unique endopeptidase enzyme that helps protect sensitive gastrointestinal tissue from irritation and subsequent inflammation that can adversely affect tissue health and intestinal comfort.

## Degrades yeast cell walls and promotes microbial balance

InterFase® formulations contain enzymes with powerful lytic activity on cell walls of fungi. A highly specific beta-1,3-glucanase is included that disrupts the difficult-to-penetrate beta-glucan linkages comprising almost 95% of yeast cell walls. Lysozyme, an antibacterial enzyme found in tears, human breast milk, saliva, nasogastric, and bronchial tissue, promotes protective barrier function by degrading polysaccharides found in the cell walls of many undesirable bacteria and yeast. In the gastrointestinal tract, lysozyme's action helps support a balanced microbial population.



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## Adjunctive support for management of intestinal microorganisms

InterFase® and InterFase® Plus are intended for use in conjunction with efforts to support normal gastrointestinal function and microbiota. As adjuncts to other efforts to balance gut microorganisms, they are best combined with use of a high-CFU, multispecies probiotic formulation such as Ther-Biotic® Complete and a prebiotic such as BiotaGen® or Galactomune® to encourage the formation of healthy intestinal microbial biofilm communities. InterFase® and InterFase® Plus may also be combined with other agents that are active in balancing microbial populations.

The suggested daily amount is 1 capsule of InterFase®, 1 to 4 times daily or 2 capsules of InterFase® Plus, 1 to 4 times daily depending on age and size.

*InterFase® enzymes are optimally used in a regimen with other microbial balancing agents to ensure biofilm is degraded. Prebiotics and probiotics support the healthy intestinal microbiota and support healthy biofilm.*



The capsules should be taken away from meals to maximize the enzyme effects.

### InterFase® Plus: Added benefits from disodium EDTA

The presence of calcium, iron, and magnesium is essential for biofilm creation and serves to cross-link the anionic regions of polymers. InterFase® Plus includes ethylenediaminetetraacetic acid (EDTA), which binds the metals needed for biofilm formation and integrity. Disodium EDTA damages the structure of bacterial cell membranes making them more permeable to agents that are active in balancing microbial populations. The combination of EDTA and hydrolytic enzymes in InterFase® Plus produces a more potent antibiofilm effect than either agent used alone.

## Nutritional Adjuncts to Support Gastrointestinal Detoxification & Microbial Balance

Product	Actions	Key Ingredient(s)	Suggested Use
InterFase® InterFase® Plus	Degrades biofilm communities by shifting the balance of gut microbiota	ENZYMES: Polysaccharidases, proteases, lysozyme ENZYMES and EDTA	Supports management of intestinal microorganisms
Ther-Biotic® Detoxification Support	Supplies beneficial microbiota that support mucosal immunity and intestinal detoxification	PROBIOTICS: 50 billion CFU	Concurrent with InterFase® or other detoxification agents
Ther-Biotic® Complete Capsules and Powder	Supplies a broad spectrum of beneficial microbiota	PROBIOTICS: 25 billion CFU (capsule) or 100 billion CFU (powder)	Concurrent with InterFase® or other detoxification agents
BiotaGen® Capsules and Powder	Supports optimum growth of beneficial bacteria, immune function, and bowel regularity	PREBIOTICS: Inulin, beta-glucan, larch arabinogalactan	Take with probiotics
Galactomune® Capsules and Powder	Supports optimum growth of beneficial bacteria, immune function, and bowel regularity	PREBIOTICS: Galactooligosaccharides, beta-glucan	Take with probiotics
Undecylex™	Encourages healthy balance of microbial populations	BOTANICALS / FATTY ACIDS: Undecylenic acid, sorbic acid, berberine-containing herbs, green tea	Use separately or with InterFase® short-term
Dual Detox™	Binds intestinal toxins and supports liver detoxification processes	BOTANICALS / ENZYMES: Chlorella, broccoli extract, enzymes	Short-term cleansing and daily balance

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## Biofilm: A Microbial Survival Mechanism

Populations of microorganisms in the human gut are divided between free-living planktonic microbes and colonizing sessile biofilm organisms. Biofilm consists of microorganisms encased within a self-produced matrix of exopolysaccharides and exoproteins that strongly adheres to interfaces and resists dislodgement. The biofilm of healthful commensal microorganisms greatly contributes to intestinal barrier function and colonization resistance.

### Biofilm protects intestinal microorganisms

Biofilm is the preferred environment for the vast majority of microorganisms. Microbes residing within biofilms may consist of 1 or more species that communicate and collaborate with one another in a heterogeneous community. Biofilm formation appears to be initiated by contact with a surface. It is a survival mechanism that triggers downregulation of genes such as those mediating motility and growth as well as expression of genes regulating synthesis of exopolysaccharides and exoproteins. The presence of calcium, iron, and magnesium is essential for biofilm creation and serves to cross-link the anionic regions of polymers.

Life within a biofilm confers significant survival advantages to bacteria and yeasts. Biofilms strongly adhere to interfaces and resist dislodgement. Biofilm formation may be viewed as an adaptive mechanism that enables microbes to persist and reproduce in an advantageous microecological niche. They are protected from predation by phages and protozoa as well as from host immune responses. (Biofilm-residing microorganisms are highly resistant to the spectrum of

agents active in balancing microbial populations ranging from germicides and disinfectants to antibiotics and bacteriocins produced by probiotics.) Sessile biofilm microorganisms are 10 to 1,000 times more resistant to antibiotics compared to planktonic forms of the same strain. Resistance of biofilm-associated organisms has been attributed to impaired penetration of the biofilm matrix, reduced microbial growth rates, biofilm-induced expression of resistance factors, and other biofilm-associated physiologic changes that decrease susceptibility to microbial balancing agents.

### Gastrointestinal biofilm – for better or worse

The human gut is home to approximately 100 trillion microorganisms consisting of unattached planktonic microbes residing in the lumen and sessile biofilm organisms colonizing the mucosa and luminal particulate matter. Among the more important species involved in gastrointestinal biofilm formation are *Bacteroides*, *Bifidobacterium*, and *Fusobacterium*. *Fusobacterium* species appear to play a key role in formation and maintenance of healthy biofilm. However, *Fusobacterium* need to be kept in check or they can unbalance biofilms because it requires association with an aerobic species in certain environments.

Healthful biofilm naturally prevents colonization and biofilm formation by less desirable microorganisms. Microbes residing within biofilms rapidly express genes associated with microbial balancing agents and are protected from both cellular and humoral immune responses. Disrupting biofilm communities is critical to successful restoration of healthful biofilm communities.

# InterFase<sup>®</sup> and InterFase<sup>®</sup> Plus

## Gastrointestinal antibiofilm enzyme formulations

### Suggested use

InterFase<sup>®</sup> and InterFase<sup>®</sup> Plus are best used as part of a comprehensive program to support gastrointestinal and gut microbiota health. Depending on age and size, take 1 capsule, 1 to 4 times daily of InterFase<sup>®</sup> or take 2 capsules of InterFase<sup>®</sup> Plus 1 to 4 times daily or as directed by a healthcare professional. Most people will require higher, more frequent doses. However, because of potential “die off” symptoms, it is best to begin with a low dose and titrate up. For maximum benefit, InterFase<sup>®</sup> and InterFase<sup>®</sup> Plus should be taken between meals and contemporaneously with a microbial balancing agent. A broad spectrum, multispecies probiotic together with a prebiotic should be part of the program. The probiotic and prebiotic should be consumed at least 1 hour before or 2 hours after InterFase<sup>®</sup> or InterFase<sup>®</sup> Plus.

### Adverse reactions

Proteolytic enzymes are sometimes anecdotally claimed to exacerbate pre-existing damage to the esophageal, gastric, or duodenal mucosa, but there is scant data in the medical literature to support these claims. One study from the mid-1980s found that bromelain could induce mucosal hemorrhage in the stomachs of rats whose gastric veins had been ligated in order to produce gastric congestion, but it is entirely unclear whether these results can be extrapolated to humans under normal, or even most abnormal, physiological circumstances. Carbohydrase enzymes may increase the intestinal production and absorption of glucose. Inhalation of InterFase<sup>®</sup> or InterFase<sup>®</sup> Plus may cause respiratory irritation.

### Drug interactions

Some forms of proteolytic enzymes have been shown to reduce platelet aggregation and thus may theoretically potentiate the effects of anticoagulant medications such as Coumadin. Proteolytic enzymes with DPP-IV activity may in theory interfere with DPP-IV inhibiting drugs. Carbohydrase enzymes may increase the intestinal availability and absorption of glucose and could potentially interfere with the efficacy of oral hypoglycemic drugs or insulin.

### Contraindications

Diabetics and persons with blood glucose dysregulation should use InterFase<sup>®</sup> or InterFase<sup>®</sup> Plus under the supervision of a healthcare professional. As a precaution, persons taking anticoagulants, anti-DPP-IV medications, oral hypoglycemic agents, or insulin, and persons with gastritis, active peptic ulcers, gastroesophageal reflux disorder, or known damage to the gastrointestinal mucosa may wish to consult with a healthcare professional before using InterFase<sup>®</sup> or InterFase<sup>®</sup> Plus. InterFase<sup>®</sup> and InterFase<sup>®</sup> Plus may not be appropriate for persons with known allergies to *Aspergillus* organisms, though non-specific yeast or mold allergies do not necessarily preclude use of fungal-based enzymes. Lysozyme is derived from egg white protein and is highly purified, however, these products may not be appropriate for persons allergic to egg white. Pregnant or nursing women should consult with a healthcare professional before using InterFase<sup>®</sup> or InterFase<sup>®</sup> Plus.

### Product supply

InterFase<sup>®</sup>: 60 or 120 vegetarian capsules per bottle.

InterFase<sup>®</sup> Plus: 60 or 120 vegetarian capsules per bottle.

### About Klaire Labs<sup>®</sup> practitioner exclusive nutraceuticals

Klaire Labs<sup>™</sup> is a proud member of the Soho Flordis International (SFI) family of brands. The Klaire Labs range of high-quality nutraceuticals is designed exclusively for healthcare professionals to empower them in providing better choices for those under their care. By focusing on providing quality nutraceuticals for clinical application, Klaire Labs is dedicated to delivering optimal health outcomes.

Klaire Labs products are based on a firm scientific foundation and medical research with an unwavering commitment to quality ensuring that active ingredients are selected based on purity, bioavailability, documented actions, and safety characteristics.

Produced under a strict quality management system in compliance with Good Manufacturing Practices (GMPs) and third-party quality certifications.



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