Bacillopeptidase F Proprietary Blend (BFPB)
A Natural Enzyme Extracted by a Patented Fermentation Production Process to Support Healthy Circulation
What is Plasmanex™?

Plasmanex™ is a dietary supplement shown to support healthy blood circulation. The active ingredient of Plasmanex™ is Bacillopeptidase F Proprietary Blend (BFPB).

The active ingredient of Plasmanex™ is Bacillopeptidase F, a natural soy enzyme extracted by using a patented fermentation production process. Plasmanex™ is manufactured by Daiwa Health Development and is registered under Patent No. JP3532503.

Blood Clot Formation

The balance between smooth uninterrupted blood flow and the protective action of clotting and clot lysis is an appropriate clot formation and clot dissolution, as the basis of coagulation control. In the case of trauma that damages blood vessels, clotting is necessary to prevent excessive blood loss. Conversely, factors such as an unhealthy lifestyle, excess calorie intake, inflammation, atherosclerosis, aging and obesity may promote excessive clot formation and lead to fatal consequences. Some congenital and hereditary defects tip the balance for a propensity towards coagulation at inopportune times. Other factors such as prolonged travel and obesity is complicated by blood clots.

How does the body maintain the fluid state of blood?

The blood constantly attempts to form fibrinogen/fibrin which is derived from a reaction with thrombin. When fibrin is produced, a clot is formed which can be either normal or pathological. The system attempts to balance itself through fibrin lysis by producing plasmin that is formed from healthy endothelial cells. The plasmin then joins forces with plasminogen that breaks down or attempts to break down the fibrin mesh at its various stages. When broken down, fibrin forms D-dimer or fibrin degradation products. The fibrin split products at various levels of concentration can be harmful to the kidney and the brain. A more precise clot regulation or modulation becomes the cornerstone for maintaining a more physiological balance. Thus the central aspect of coagulation is the formation of plasmin by healthy endothelium that breaks down thrombin and fibrin complexes to maintain normal blood flow.

The Clot Regulator: Plasmin/Plasminogen System

When blood vessels are injured and blood loss becomes a risk, enzymatic factors prompt thrombin/fibrinogen to increase. As a result, plasmin/plasminogen/t-PA react to maintain a delicate balance between bleeding and clotting. Recent findings show that the plasmin/plasminogen/t-PA system also regulates clotting and maintains fluid blood flow through the body to create a balance between the opposing factors.

Tissue Plasminogen Activator (t-PA)

t-PA, the activator, triggers clot breakdown and conversely, PAI-1, the inhibitor, triggers clot formation. Evidence shows that the overall plasmin/plasminogen balancing system is regulated by PAI-1, formerly called tissue inhibitory factor.
Plasminogen Activator Inhibitor-1 (PAI-1)

PAI-1 is the principal inhibitor in blood for the various types of t-PA. It also plays a role in regulating cell-to-cell adhesion, a process that is relevant to tissue remodeling. A hereditary deficiency in PAI-1, which is very rare, may result in a lifelong bleeding disorder. PAI-1 also inhibits dissolution of blood clots; therefore, elevated PAI-1 levels could increase the overall presence of clots due to increased formation and decreased dissolution. Consequently, increased PAI-1 levels are associated with increased risk of myocardial infarction.

The balance between thrombin and plasmin determines the clinical picture and whether it is characterized by thrombosis which signifies an excess activity of fibrin (microcirculation) and fibrinogen (blood pool) or predominantly bleeding where there is an excess of plasmin and its activating products.

Insulin Resistance and Metabolic Syndrome

Modern lifestyle and diet choices can cause weight gain and obesity, ultimately leading to Metabolic Syndrome. Overweight and obesity causes adipocytes (fat cells) to become abnormally large. Oversize fat cells generate excessive levels of enzymes, including PAI-1 and several cytokines which adversely affect the body. PAI-1 is thought to contribute to insulin resistance, causing serious health consequences, including the progression of atherosclerosis, diabetes, and hypertension.
How does Plasmanex1™ work in the body?

In vitro and in vivo studies suggest that Plasmanex1™ may reduce the unchecked production of PAI-1. The in vitro studies also suggest that Plasmanex1™ reduces other hypercoagulable factors to normal levels. It is thought that by reducing PAI-1 formation, plasmin/plasminogen is preserved, rather than increasing the formation of fibrin and fibrinogen. Hence, Plasmanex1™ is recognized as an effective Coagulation Modulator™. Recent studies have revealed that Plasmanex1™ normalized the coagulation factors at various rates. Coagulation levels did not drop below normal levels with use of Plasmanex1™. On the other hand reducing production of procoagulant factors and reduction of unwanted wasted overuse of plasmin can be a desirable modulation of coagulation status. Eventually most, if not all, patient coagulation factors return to normal without a potential or a tendency towards excessive bleeding. Plasmanex1™ assisted in the normalization of coagulation.

An in vitro study conducted at the Nagoya University of School of Medicine, Nagoya, Japan, suggests that Plasmanex1™ inhibits the production of PAI-1 in U87-MG cells in a dose dependent manner.

In some studies on patients with acute coagulation changes, the use of Plasmanex1™ caused an increase in t-PA activity, an enzyme which acts to rapidly break down newly formed blood clots in the blood vessels, and promotes plasmin viability. High C-reactive protein (CRP) levels in patients were reduced, indicating a reduction in vascular inflammation or excessive lipid accumulation which correlated with decreased PAI-1 activity. This activity leads to increased t-PA levels, and ultimately increases clot dissolution activity. Plasmanex1™ restores the PAI-1/t-PA balance and lowers overall clot levels of fibrin and fibrin degradation products.
What conditions promote blood clot formation?
The following conditions may cause clot formation:

• Hyperlipidemia (Especially High Triglycerides, Low HDL and High LDL)
• Diabetes
• Inflammation
• Viral, Fungal and Bacterial Infections
• Autoimmune Diseases
• Allergies
• Obstructive Sleep Apnea
• Pulmonary Hypertension
• Heart Failure and Left Ventricular Systolic Dysfunction (LVSD)
• Venous Stasis
• Varicose Veins and Deep Vein Thrombosis
• Lifestyle Factors such as Obesity, Aging, Dehydration, Pregnancy, Cardiovascular Disease
• Cancer of Various Forms such as Prostate, Pancreas and Colon
• Cancer Treatment including Cancer Drugs and Radiation Therapy

What are the primary actions of Plasmanex™?
Plasmanex™ has three primary functions, as confirmed through several studies:

• Balancing the blood flow dynamics through PAI-1 and tPA
• Retarding thrombosis in abnormal coagulation states only
• Decreasing blood viscosity through reduction of fibrinogen

The actions of preventing thrombus formation and decreasing blood viscosity make Plasmanex™ unique.

Plasmanex™ Recommended Dosage
Plasmanex™ is recommended for healthy blood circulation. As a dietary supplement, the recommended dosage is one or two capsules before bedtime, or one in the morning and one at night. One capsule a day is recommended when Plasmanex™ is to be used chronically and the possibility of a history of bleeding exists but is not certain.
These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Plasmanex1™ Product Guideline

Plasmanex1™ is not recommended for those who have the following health issues:

• Anemia with Hemoglobin Below 12.5 gm/dl
• History of Bleeding Due to Peptic Ulceration of the Gastric Mucosa
• History of Bleeding Colonic Polyps
• History of Significant Urinary or Vaginal Bleeding
• Recent History of Major Head Injury
• Recent History of a Major Trauma
• Platelet Counts Below 150,000
• Active Systemic Lupus Erythematosus (SLE or Lupus)
• Active Warfarin (Coumadin) or Advanced Anti-Platelet Therapy
• Use of Large Doses of Aspirin or Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)
• Active Leukemia
• Advanced Systemic Bacterial Infections

These conditions are contraindicated to the use of Plasmanex1™. Following the administration of Plasmanex1™, a physician should check hemoglobin levels regularly every two or three months and platelet count every six months.

Safety Studies

Twenty-three healthy adults were given 250mg of Plasmanex1™ daily for 12 weeks in a study conducted at the Department of Legal Medicine, Dokkyo University School of Medicine, Mibu, Japan, and Hanzomon Gastrointestinal Clinic, Tokyo, Japan. No clinical adverse effects were observed.

A toxicity study was conducted by the Department of Legal Medicine, Dokkyo University School of Medicine, Mibu, Japan, Sekokay S.S. Clinic, Hachioji, Japan and Department of Strategic Management/IT, Chiba University of Commerce, Chiba, Japan. Eight healthy adults were given excess intake of 1,250 mg of Plasmanex1™ daily for 7 days. No clinical adverse effects were observed. Additional safety information is available upon request.

Plasmanex1™ Patent Pending Applications

Daiwa Pharmaceutical Co., Ltd., Tokyo, Japan, the parent company of Daiwa Health Development Inc. U.S.A., has applied for U.S. Patent Application No. 20060105071 referencing the Bacillopeptidase F Proprietary Blend™ (BFPB) as a blood viscosity reducing agent. Daiwa also has filed a patent in Japan for BFPB as a blood viscosity reducing agent (JP 2004-331559).