BRODASE TABLET

COMPOSITIONS:

Each enteric coated tablet contains:

Trypsin B.P. 48mg.
Bromelain 90mg.
Rutoside Trihydrate B.P. 100mg.

TRYPSIN

Trypsin is a proteolytic enzyme which is essential regulators and modulators of the inflammatory response. Proteolytic enzymes also degrade pathogenic complexes that can inhibit normal immune function. These immune complexes, which consist of an antigen bound to an antibody, are a normal part of the immune response. But when immune complexes occur in excess, they are a principal cause of certain kidney diseases, nerve inflammations, and a number of rheumatologic diseases, including rheumatoid arthritis. Evidence suggests that trypsin, papain, and other proteolytic enzymes can break up existing pathogenic immune complexes and even prevent their formation in the first place, enhancing lymphatic drainage. The bottom line of these actions is a regulatory or stimulatory effect on the immune system.

Proteolytic enzymes modulate the inflammatory process by a variety of mechanisms, including reducing the swelling of mucous membranes, decreasing capillary permeability, and dissolving blood clot-forming fibrin deposits and microthrombi.

Clinical studies exhibit that the anti-inflammatory effect of trypsin is possibly due to inhibitory action on the vascular permeability and its ability to inhibit the rise in C-reactive protein and enhance the rise in alpha 1-antitrypsin, alpha 2-macroglobulin.

Trypsin improves blood circulation by reducing viscosity of the blood. This consequently increases the supply of oxygen and nutrients to and the transport of harmful waste products away from traumatized tissue. Proteolytic enzymes also help break down plasma proteins and cellular debris at the site of an injury into smaller fragments. This greatly facilitates their passage through the lymphatic system, resulting in more rapid resolution of swelling, with the consequent relief of pain and discomfort.

BROMELAIN:

Bromelain is a mixture of several protein-digesting enzymes along with other types of enzymes, enzyme inhibitors and calcium. It is found in pineapple juice and in the pineapple stem, although it exists in all parts of the fresh plant and fruit. The term "**Bromelain**" may refer to either of two protease enzymes extracted from the plants of the family Bromeliaceae, or it may refer to a combination of those enzymes along with other compounds produced in an extract.

MECHANISM OF ACTION OF BROMELAIN:

Bromelain increases blood fibrinolytic activity as well as inhibiting fibrinogen synthesis; bromelain also directly degrades fibrin and fibrinogen. Kininogen and bradykinin serum and tissue levels are lowered by bromelain and it also affects prostaglandin synthesis, which gives its anti-inflammatory effects. Bromelain has been found to reduce the excretion of proinflammatory cytokines as well as chemokines.

In vitro and in vivo studies demonstrate that bromelain exhibits various fibrinolytic, antiedematous, antithrombotic, and anti-inflammatory activities. Bromelain is considerably absorbable in the body without losing its proteolytic activity and without producing any major side effects. Bromelain accounts for many therapeutic benefits like the treatment of angina pectoris, bronchitis, sinusitis, surgical trauma, and thrombophlebitis, debridement of wounds, and enhanced absorption of drugs, particularly antibiotics. It also relieves osteoarthritis, diarrhea, and various cardiovascular disorders. Bromelain also possesses some anticancerous activities and promotes apoptotic cell death. It removes dead and damaged tissue after a burn (debridement), prevent the collection of water in the lung (pulmonary edema).

Use in Pregnancy: Not recommended.

<u>Use in nursing women</u>: Not recommended.

SIDE EFFECTS OF BROMELAIN:

Diarrhea, Stomach and intestinal discomfort, May cause allergic reactions.

Special Precautions while taking Bromelain:

<u>Allergies</u>: Allergic to pineapple, wheat, celery, papain, carrot, fennel, cypress pollen or grass pollen, might have an allergic reaction to Bromelain.

<u>Surgery</u>: Bromelain might increase the risk of bleeding during and after surgery. Stop using bromelain at least 2 weeks before a scheduled surgery.

DRUG INTERACTION:

- 1. Taking bromelain along with Penicillin group of antibiotics might increase the effects and side effects of Penicillin like Amoxicillin.
- 2. Taking bromelain along with Macrolides group of antibiotics like tetracycline might increase effects and side effects of these antibiotics.
- 3. Taking Bromelain along with medications that also slow clotting might increase the chances of bruising and bleeding.

RUTOSIDE

Rutoside is a natural flavone derivative. It has anti-inflammatory, anti-allergy and immunomodulating activity. Rutoside inhibits platelet aggregation, as well as decreasing capillary permeability, making the blood thinner and improving circulation. Rutin also strengthens the capillaries. It helps to prevent venous edema of the legs. Thus, rutoside is useful in the management of venous edema and capillary fragility. Rutoside is powerful anti-oxidants and effectively combat the harmful free radicals such as nitric oxide that released during the inflammatory process. Rutoside also suppresses the major inflammatory and proarthritic mediators of macrophages.

Pharmacokinetics:

Absorption: Only about 17% of an ingested dose is absorbed.

Metabolism: Hepatic.

SIDE EFFECTS:

Headache, Flushing, Rashes, Stomach upset.

CONTRAINDICATIONS:

It is contraindicated in those who are hypersensitive to any component of a rutin containing product.

PREGNANCY AND LACTATION:

Not indicated.

DRUG INTERACTION:

No information available.

BRODASE TABLET:

DESCRIPTION:

Brodase Tab. contains a combination of two proteolytic enzymes Trypsin and Bromelain together with plant flavonoid Rutoside. This combination has anti-inflammatory and analgesic and antioxidant property. It ensure very promising role in relieving pain and inflammation and provide faster wound healing. Many clinical studies revealed that this combination is one of the best alternatives of NSID's with minimum adverse effects.

INDICATIONS:

Brodase Tab. is indicated for treatment of edema and inflammation of traumatic condition such as bruise, tear in skin and cuts. It is also indicated for treatment of edema and inflammation following surgery, tooth extraction, cellulitis, abscess, sport injuries and sprains. Brodase Tab. is indicated for inflammatory conditions such as Rheumatoid Arthritis, Osteoarthritis, Spondylopathies, Tendonitis and Bursitis.

DOSAGE:

<u>Adult</u>: 6 tablets of Brodase/day i.e. 2 tablets three times a day, is recommended for adult patients 1- 2 hours before food.

<u>Children</u>: Children 6 years and above, 1 tablet/ 10kg body weight/ day up to maximum 6 tablet a day. Total recommended dose is administered in 2-3 divided doses.

SIDE EFFECTS:

Brodase Tablet is usually well tolerated. Harmless alteration in the consistency, color and odor of stool may occur. A sensation of fullness, flatulence, and occasional episodes of nausea are possible during high-dosage administration. They can be avoided by administration of the enzyme preparation in divided doses during a day. If these symptoms persist then seek to medical attention. Allergic reaction occurs rarely and disappears after the discontinuation of the drug. In case of their occurrence continue after discontinuation of Brodase Tablet then doctor should be consulted.

DRUG INTERACTIONS:

No clinical trials have been conducted to evaluate the drug interaction. However, no evidence of incompatibility of this combination with other simultaneously administered drugs has been reported. Care should be exercised while this medicine with Penicillin and Macrolides group of antibiotics.

CONTRAINDICATION:

Brodase Tab. must not be used in case of known hypersensitivity to its active ingredients. The preparation must not be used by patients with severe inborn or gained coagulation disorders. (E.g- hemophilia, severe liver damage, dialyzed patients).

PREGNANCY AND LACTATION:

Brodase Tab. is not recommended during pregnancy and breastfeeding.

STORAGE CONDITION:

Store in a cool and dry place away from direct sunlight.

PRESENTATION:

Brodase tablet is available 1*10 in an Alu-Alu strip and 10 strips in a carton.