

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Kontab Tablet

2. Qualitative and quantitative composition

Each enteric coated tablet contains:

Bromelain 20,000 units(50mg)

Crystallien Trypsin 2500 USNF units(1mg)

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Enteric coated tablet

Apple green round biconvex enteric coated tablets.

4. Clinical particulars

4.1 Therapeutic Indications:

Kontab is indicated as an adjunct in the treatment of Soft Tissue Inflammation and edema associated with Trauma and surgery such as Gynecological conditions, Breast engorgement, Fractures, Sprains, Injuries, Hemorrhoid, Axial prolapsed, and other inflammatory conditions where anti-inflammatory enzyme preparations are indicated.

Mechanism of action:

Bromelain Mechanism of action:

The pineapple protease, bromelain, selectively inhibits the biosynthesis of pro inflammatory prostaglandins, apparently by indirect action. The inhibition of endogenous proteases that accompanies trauma or prolonged exposure to excessive stress markedly elevates the relative proportions of those prostaglandins responsible for the symptoms of inflammation.

Trypsin Mechanism of Action:

Trypsin, [enzyme](#) that acts to degrade [protein](#); it is often referred to as a proteolytic enzyme, or proteinase. Trypsin is one of the three principal digestive proteinases, the other two being [pepsin](#) and [chymotrypsin](#). In the digestive process, trypsin acts with the other proteinases to break down dietary protein molecules to their component peptides and amino acids. Trypsin continues the process of digestion (begun in the stomach) in the small intestine where a slightly alkaline environment (about $pH 8$) promotes its maximal enzymatic activity. Trypsin, produced in an

inactive form by the pancreas, is remarkably similar in chemical composition and in structure to the other chief pancreatic proteinase, chymotrypsin. Bromelains and trypsin therefore acts as a proteolytic enzymes which catalyse the hydrolysis of protein, polypeptides, amides, and eserts at bonds involving the carboxyl group or L-arginine and L-Lysis, it is therefore used for the removal of coagulated blood, exudates and necrotic tissue. Bromelains has also been suggested to have spasmolytic effect.

4.2 Posology and Method of Administration:

Route of administration: ORAL

Initially two (2) tablet daily three times a day. For maintenance one tablet three times daily preferably before meal.

4.3 Contraindications

Kontab is contraindicated in patients with known history of hypersensitivity. Kontab tablets are also contra-indicated in pregnancy and lactation. Kontab tablets are not recommended for people with active gastric or duodenal ulcers. People taking anticoagulant drugs such as warfarin should not take Kontab tablets without consulting their physician.

Kontab Tablet is contraindicated in severe heart failure. The selective inhibitors of cyclo-oxygenase-2 (celecoxib, etoricoxib and parecoxib) are contraindicated in ischaemic heart disease, cerebrovascular disease, peripheral arterial disease and moderate or severe heart failure. The selective inhibitors of cyclo-oxygenase-2 should be used with caution in patients with a history of cardiac failure, left ventricular dysfunction, hypertension in patients with oedema for any other reason, and in patients with risk factor for heart disease

4.4 Special Warning and Precautions for Use:

Warnings

People taking anticoagulant drugs such as warfarin should not take Kontab tablet without consulting their physician.

Precautions

Kontab is contraindicated in patients with bleeding disorders, renal and/or hepatic disorders. People taking anticoagulant drugs such as warfarin should not take supplementary Bromelain without consulting their physician.

People who are allergic to pineapples, wheat, celery, papain, carrot, fennel, cypress pollen, or grass pollen may also be allergic to Bromelain.

Kontab should be avoided in patients with asthma, peptic ulcer, liver or kidney disease, high blood pressure.

Kontab Tablet is contraindicated in severe heart failure. The selective inhibitors

of cyclo-oxygenase-2 (celecoxib, etoricoxib and parecoxib) are contraindicated in ischaemic heart disease, cerebrovascular disease, peripheral arterial disease and moderate or severe heart failure. The selective inhibitors of cyclo-oxygenase-2 should be used with caution in patients with a history of cardiac failure, left ventricular dysfunction, hypertension in patients with oedema for any other reason, and in patients with risk factor for heart disease.

4.5 Drug Interactions:

People taking anticoagulant drugs such as warfarin should not take supplementary Bromelain without consulting their physician. Bromelain may also **enhance the effect of the antibiotics** amoxicillin, erythromycin, penicillamine, and penicillin.

The concurrent administration of NSAIDs and Kontab Tables leads to decrease in the blood concentration of the later ,and an increase in side- effects.

4.6 Uses in Pregnancy and Lactation:

Pregnancy

Not enough is known about the use of Kontab Tablets during pregnancy and breast-feeding. Stay on the safe side and avoid use.

Breastfeeding

Not enough is known about the use of Kontab tablet during pregnancy and breast-feeding. Stay on the safe side and avoid use.

4.7 Effects on ability to drive and use machine:

No such data is available for now.

4.8 Undesirable Effects:

Kontab Tablets may cause nausea, vomiting, and diarrhoea. Metrorrhagia and menorrhagia have occasionally occurred. Hypersensitivity reactions have been reported and have included skin reactions and asthma.

Bronchial asthma was experienced by 2 patients after exposure to bromelains.¹ Of 6 workers sensitised to papain, 5 showed positive skin tests to bromelains and 2 of them also showed immediate asthmatic reactions after bronchial challenge with bromelains.

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

4.9 Overdoses & special antidotes:

In cases of overdosage with Kontab Tablets, management is supportive. Further

administration is stopped and activated charcoal is given by mouth to bind the remaining drugs in the gastrointestinal system thereby reducing their absorption. The usual adult dose of activated charcoal is 50g initially then 50g every 4 hours.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties

Bromelain and Trypsin acts as a proteolytic enzymes which catalyse the hydrolysis of protein, polypeptides, amides, and eserts at bonds involving the carboxyl group or L-arginine and L-Lysis, it is therefore used for the removal of coagulated blood, exudates and necrotic tissue. Bromelains has also been suggested to have spasmolytic effect.

5.3 Pre-clinical safety data:

Not applicable as it is generic product.

5.2 Pharmacokinetic Properties:

Bromelain is absorbed through the gastrointestinal tract. It was detected (up to 40%) in blood after oral administration in rats. Bromelain concentration was found highest in the blood after one hour of administration. It is also reported that upto to 40% of Bromelain is absorbed from the intestine. In an experimental study it is determined the half-life (6-9hr) and plasma concentration (2.5-4mg/ml) of Bromelain after oral administration of 8.6g each day. As Kontab is an enzymatic preparation its complete pharmacokinetics studies are still unknown.

6. Pharmaceutical Particulars:

6.1 List of Excipients

1. Lactose Monohydrate (200)
2. Mannitol
3. Maize Starch (Dried)
4. Polyvinylpyrrolidone (K30)
5. Methacrylic Acid Copolymer (L100)
6. Isopropyl Alcohol
7. Magnesium Stearate
8. Shellac
9. Solvent EDibutyl Phthalate
10. Purified Talc

11. Kaolin (Light)
12. Acacia (Gum)
13. Gelatin
14. Sucrose (Sugar Crystalline)
15. Polyethylene Glycol (6000)
16. Polyethylene Glycol (35000)
17. Opalux Green (AS51134)
18. Titanium Dioxide
19. Polyvinylpyrrolidone (K30)
20. Carnauba Wax
21. Purified water

6.2 Incompatibilities

None Applicable

6.3 Shelf life

3 years from the date of manufacture

6.4 Special precautions for storage

- Store in a cool and dry place away from sun light
- Keep all medicines out of reach of children
- Store below 30° C.

6.5 Nature and contents of container

- Blister pack of 50 tablets 5 X 10's in sachet foil.

7. Marketing Authorization Holder:

Efroze Chemical Industries (Pvt) Ltd.

146/23 Korangi Industrial Area,

Karachi – Pakistan

8. Marketing Authorization Number

CTD9441.

9. Date of first authorization/renewal of the authorization

22/01/2026

10. Date of revision of the text

22/01/2026