1. Name of the medicinal product:
ETOVAC-SP

2. Qualitative and quantitative composition
Each film coated tablets contains:

Etoricoxib	60mg
Serratiopeptidase	10mg

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM
Film Coated Tablet

4.CLINICAL PARTICULARS
4.1 Therapeutic indications
ETORICOXIB+SERRATIOPEPTIDASE belongs to the class of drugs known as pain killer/ 'non-steroidal anti-inflammatory drug' (NSAID). ETORICOXIB+SERRATIOPEPTIDASE is used to provide pain relief in various conditions including post-traumatic pain, low back pain, cervical pain, spondylitis (inflammation in spinal bones), osteoarthritis (joint pain and stiffness), rheumatoid arthritis (joint pain and damage throughout the body), migraine, etc. Pain can be temporary (acute) or prolonged period (chronic) in nature. Acute pain is for a short time caused by damage to the tissues of the muscle, bone or organs. Chronic pain lasts for long time caused due to nerve damage, osteoarthritis, dental pain, etc., due to damage to the tooth nerve, infection, decay, extraction or injury. ETORICOXIB+SERRATIOPEPTIDASE contains two medicines namely etoricoxib and serratiopeptidase. ETORICOXIB+SERRATIOPEPTIDASE contains 'etoricoxib' which works by blocking the release of a chemical messenger called prostaglandin, produced by COX-2, which is responsible for pain, swelling and inflammation. Serratiopeptidase is a proteolytic enzyme which helps in the breakdown of insoluble protein (fibrin) a by-product of blood clot into smaller units. It also causes thinning of the fluids in the body as a result of injury, thereby making fluid drainage smoother in the swollen tissue. Together ETORICOXIB+SERRATIOPEPTIDASE is effective for relieving pain.

4.2 Posology and method of administration Posology:

Take ETORICOXIB+SERRATIOPEPTIDASE as prescribed by your doctor. You are advised to take ETORICOXIB+SERRATIOPEPTIDASE for as long as your doctor has prescribed it for you depending on your medical conditions. You may experience stomach pain, diarrhea, flatulence, indigestion, feet swelling, swelling of hands and flu-like symptoms. Most of these side effects of ETORICOXIB+SERRATIOPEPTIDASE do not require medical attention and gradually resolve over time. However, if the side effects are persistent, reach out to your doctor.
Do not take ETORICOXIB+SERRATIOPEPTIDASE if you are allergic to ETORICOXIB+SERRATIOPEPTIDASE, other pain killers or any other ingredients present in it. ETORICOXIB+SERRATIOPEPTIDASE should not be taken in the conditions like ulcers or bleeding in your stomach, severe liver and/or kidney impairment, colitis (inflammation of the large intestine), uncontrolled blood pressure, heart problems such as chest pain, heart attack or heart failure and stroke. ETORICOXIB+SERRATIOPEPTIDASE is not recommended for children below 16 years of age. Before taking ETORICOXIB+SERRATIOPEPTIDASE inform your doctor if you are more than 65 years of age. Inform your doctor immediately if you are pregnant, planning to become pregnant or breastfeeding

Method of administration
For oral administration only.
Swallow ETORICOXIB+SERRATIOPEPTIDASE as a whole with water; do not crush, break or chew it.

4.3 Contraindications
Use of ETORICOXIB+SERRATIOPEPTIDASE is contraindicated in kidney failure patients or who are undergoing dialysis. Inform your doctor if you are dehydrated (because of vomiting or diarrhea), have edema (swelling due to fluid retention).

4.4 Special warnings and precautions for use
Drug Warning
Before taking ETORICOXIB+SERRATIOPEPTIDASE, inform your doctor if you have a history of stomach bleeding or ulcer, liver or kidney diseases, dehydration because of prolonged vomiting or diarrhea and swelling due to fluid retention. Inform your doctor if you have high blood pressure that is not treated or controlled as ETORICOXIB+SERRATIOPEPTIDASE may increase blood pressure in some cases. Do not take ETORICOXIB+SERRATIOPEPTIDASE if you are treated for infection as ETORICOXIB+SERRATIOPEPTIDASE can mask fever (a

sign of infection). Use of ETORICOXIB+SERRATIOPEPTIDASE is contraindicated in kidney failure patients or who are undergoing dialysis. Inform your doctor if you are dehydrated (because of vomiting or diarrhea), have edema (swelling due to fluid retention). Patients who have had recently undergone heart bypass surgery should take ETORICOXIB+SERRATIOPEPTIDASE with caution and only under medical supervision. Do not take ETORICOXIB+SERRATIOPEPTIDASE if you smoke, have diabetes (high blood sugar) or high cholesterol as ETORICOXIB+SERRATIOPEPTIDASE increases the risk of heart attack or stroke. Avoid lying down for at least half an hour after using ETORICOXIB+SERRATIOPEPTIDASE. People who have had any heart attack and stroke in the past should not take ETORICOXIB+SERRATIOPEPTIDASE. Do not drive or operate heavy machinery as intake of ETORICOXIB+SERRATIOPEPTIDASE may cause dizziness.

4.5 Interaction with other medicinal products and other forms of interaction

Drug-Drug Interactions: ETORICOXIB+SERRATIOPEPTIDASE may interact with anticoagulant (warfarin, heparin, aspirin, clopidogrel), immunosuppressant (methotrexate), antihypertensives (enalapril, ramipril, losartan, valsartan, and minoxidil), medicines used for mood swings (lithium), antimalarial (primaquine), a medicine used to prevent pregnancy (ethinyl estradiol).

Drug-Food Interactions: Drinking alcohol should be avoided while taking ETORICOXIB+SERRATIOPEPTIDASE as it can cause unpleasant effects.

Drug-Disease Interactions: ETORICOXIB+SERRATIOPEPTIDASE should be used with caution in patients with stomach ulcers or bleeding, severe kidney disease, liver diseases, colitis (inflammation of the large intestine), uncontrolled blood pressure, heart failure, stroke and other heart problems.

4.6. Fertility, Pregnancy and lactation

Pregnancy

ETORICOXIB+SERRATIOPEPTIDASE shows toxic effects on the fetus when given to pregnant women. ETORICOXIB+SERRATIOPEPTIDASE may impair female fertility and is not recommended in pregnant women or those planning for pregnancy. Consult your doctor for further advice.

Breast feeding

ETORICOXIB+SERRATIOPEPTIDASE passes into the breast milk, so it is not recommended for nursing mothers. Consult your doctor for further advice.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects:

Musculoskeletal pain: Different types of musculoskeletal pain are caused due to soft tissues (muscle, tendon, and ligaments) injury. Extreme tissue pain and inflammation caused due to sprains, strains, trauma or post-surgery may require a prolonged amount of time to heal. Different types of musculoskeletal pain are caused due to soft tissues (muscle, tendon, and ligaments) injury. Extreme tissue pain and inflammation are caused due to sprains, strains or trauma or post-surgery. These types of injuries may require a prolonged amount of time to heal.

Osteoarthritis: Osteoarthritis is the common type of arthritis in which the cartilage that cushions the ends of the bones erodes due to wear and tear over time. Common symptoms are joint pain and stiffness.

Rheumatoid arthritis (RA): Rheumatoid arthritis (RA) is an autoimmune disease in which the immune cells attack the joints and cause bone erosion leading to severe pain and swelling. It may lead to joint deformity if left untreated.

Ankylosing spondylitis: Ankylosing spondylitis is a type of arthritis in which inflammation is seen in the spine and large joints. It leads to pain and stiffness in the back and affected joints.

Gout: Gout is an inflammatory condition in which uric acid deposits and crystallizes in the joints. It is characterized by acute, severe and recurring attacks of pain, especially at night, redness and swelling in the affected joints

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important.It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the marketing authorisation holder, or, if available, via the national reporting system.

4.9 Overdose

Symptoms: stomach pain, diarrhea, flatulence, indigestion, feet swelling, swelling of hands and flu-like symptoms.

Treatment: gastric lavage and general supportive measures.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: non-steroidal anti-inflammatory drug' (NSAID).; ATC Code: M01AH05

Mode of Mechanism of Etoricoxib:

Like any other selective COX-2 inhibitor ("coxib"), etoricoxib selectively inhibits isoform 2 of the enzyme cyclooxygenase (COX-2). It has approximately 106-fold selectivity for COX-2 inhibition over COX-1.[10] This reduces the generation of prostaglandins (PGs) from arachidonic acid. Among the different functions exerted by PGs, their role in the inflammation cascade should be highlighted.

Selective COX-2 inhibitors show less activity on COX-1 compared to traditional non-steroidal anti-inflammatory drugs (NSAID). This reduced activity is the cause of reduced gastrointestinal side effects, as demonstrated in several large clinical trials performed with different coxibs.

Mode of Mechanism of Serratiopeptidase:

ATC Code: M09AB

The oral administration of serratiopeptidase tablets reduce pain and inflammation. The enzyme has its mode of action on arachidonic acid pathway (COX I and COX II), and acts on the cyclooxygenase pathway, but not on the lipooxygenase pathway (LOX).

5.2 Pharmacokinetic properties

Adsorption

Serratiopeptidase: The intestinal absorption of serratiopeptidase has been tested in rats by evaluating its concentration in plasma, lymph, and inflammatory tissue extract using the sandwich enzyme immunoassay technique. The study showed that the concentration of serratiopeptidase in plasma and lymph is dose dependent.

Etoricoxib: Orally administered etoricoxib is well absorbed. The absolute bioavailability is approximately 100%. Following 120 mg oncedaily dosing to steady state, the peak plasma concentration (geometric mean Cmax = 3.6 μg/ml) was observed at approximately 1 hour (Tmax) after administration to fasted adults.

Distribution

Serratiopeptidase: Distributed throughout the body tissues, unchanged via systemic circulation. It reaches in higher concentration in inflamed tissues.

Etoricoxib: Etoricoxib is extensively protein bound, primarily to plasma albumin, and has an apparent volume of distribution of 120 L in humans. The area under the plasma concentration-time curve (AUC) of etoricoxib increases in proportion to increasing oral doses between 5 and 120 mg

Metabolism

Serratiopeptidase: The oral administration of serratiopeptidase tablets reduce pain and inflammation. The enzyme has its mode of action on arachidonic acid pathway (COX I and COX II), and acts on the cyclooxygenase pathway, but not on the lipooxygenase pathway (LOX).

Etoricoxib: Etoricoxib is metabolized primarily by the cytochrome P450 (CYP) 3A4 isoenzyme. Plasma concentrations (AUC) of etoricoxib appear not to be different in patients with chronic renal insufficiency compared with individuals who have normal renal function.

Excretion

Serratiopeptidase: Elimination of excessive inflammation with potent (serratiopeptidase-containing) systemic enzyme formulations may reduce the size of fibroids by limiting vascularization of fibroids and by enzymatic myolysis of the fibroid. Such systemic enzymes are Neprinol, Wobenzym, Vitalzyme, and bromelain (from pineapple stems).

Etoricoxib: Etoricoxib is eliminated following biotransformation to carboxylic acid and glucuronide metabolites that are excreted in urine and faeces, with little of the drug (<1%) being eliminated unchanged in the urine. Etoricoxib is metabolized primarily by the cytochrome P450 (CYP) 3A4 isoenzyme.

5.3 Preclinical safety data

Non-Clinical reveal on safety data.

6.PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. No.	Name of Ingredients	Specifications
1	Di-Basic Calcium Phosphate	BP
2	Maize Starch	BP
3	Microcrystalline Cellulose	BP
4	PVP K-30	BP
5	Methyl Paraben	BP
6	Propyl Paraben	BP
7	Purified Water**	BP
8	Purified Talc	BP
9	Magnesium Stearate	BP
10	Sodium Starch Glycolate	BP
11	Colloidal Anhydrous Silica	BP
12	Hydroxypropyl Methyl Cellulose	BP
13	Iso-Propyl Alcohol	BP
14	Methylene Dichloride	BP

15	Titanium Dioxide	BP
16	Colour: Erythrosine Supra	IH
17	Mono-Propylene Glycol	BP

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30°C. Protect from light & moisture.

6.5 Nature and contents of container
10 Tablets are packed in a ALU/ALU blister, such 3 blisters are packed in carton with insert.

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
PROMED PHARMACEUTICALS LTD
P.O BOX 22953-00100
Nairobi, Kenya

Manufacturer:
ZAIN PHARMA LTD.
Plot No: 209/13741, Colchester Park,
Go-Down No.1, 2, 3, Off Mombasa Road,
Behind Nice And Lovely House,
P.O. Box: 100167-00101, Nairobi, Kenya

8. Marketing Authorization Number:
H2026/CTD12251/26528
9. Date of First <Registration> / Renewal
18/01/2026

10. Date of Revision of the Text:

18/01/2026