SUMMARY OF PRODUCT CHARACTERISTICS
ETOVAC-SP (Etoricoxib 60 mg / Serratiopeptidase 10 mg Film-Coated Tablets)

1. NAME OF THE MEDICINAL PRODUCT

ETOVAC-SP (Etoricoxib 60 mg and Serratiopeptidase 10 mg equivalent to 20,000 Units Film-Coated Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains etoricoxib 60 mg and serratiopeptidase 10 mg (as enteric-coated granules, equivalent to 20,000 serratiopeptidase units).

Excipients with known effect:

Contains methylparaben and propylparaben. For warnings, see section 4.4.

Contains erythrosine supra (a colouring agent). For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Pink, round, biconvex, film-coated tablet, plain on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ETOVAC-SP is indicated for relief of pain and inflammation associated with:

- Osteoarthritis (hip and knee).
- Rheumatoid arthritis.
- Ankylosing spondylitis.
- Musculoskeletal and soft tissue pain and inflammation (post-traumatic, low back pain, cervical pain, spondylitis).
- Acute gouty arthritis.
- Migraine.

4.2 Posology and method of administration

Adults

One tablet once daily, taken orally with water. The lowest effective dose should be used for the shortest duration necessary to control symptoms. The need for continued therapy should be periodically reassessed.

Elderly

No dose adjustment required; however, the lowest effective dose should be used.

Renal impairment

Use with caution in mild to moderate renal impairment. Etoricoxib is not recommended in patients with severe renal impairment (CrCl <30 ml/min) not on dialysis. Use is contraindicated in patients with renal failure on dialysis.

Hepatic impairment

Use with caution; dose reduction or increased dosing intervals should be considered in moderate hepatic impairment. Use is contraindicated in severe hepatic impairment.

Paediatric population

Not recommended in children below 16 years of age.

Method of administration

Oral. Swallow tablets whole with water; do not crush, break or chew.

4.3 Contraindications

- Hypersensitivity to etoricoxib, serratiopeptidase or to any of the excipients listed in section 6.1.

- Active peptic ulceration or gastrointestinal bleeding.
- Patients who have experienced asthma, urticaria, or other allergic-type reactions after taking acetylsalicylic acid or other NSAIDs (including COX-2 inhibitors) — risk of severe bronchospasm.
- Severe hepatic or renal impairment.
- Inflammatory bowel disease (Crohn's disease or ulcerative colitis).
- Congestive heart failure (NYHA II–IV).
- Established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
- Uncontrolled hypertension (persistently elevated SBP >140 mmHg or DBP >90 mmHg despite antihypertensive therapy).
- Patients undergoing coronary artery bypass graft (CABG) surgery (perioperative use).
- Renal failure / dialysis.
- Pregnancy (from 20 weeks of gestation onward — may cause oligohydramnios; contraindicated from 30 weeks onward).
- Breast-feeding.

4.4 Special warnings and precautions for use

Cardiovascular effects

NSAIDs, including etoricoxib, may increase the risk of serious cardiovascular thrombotic events, myocardial infarction and stroke, which can be fatal. This risk may increase with duration of use and dose, and may be greater in patients with pre-existing cardiovascular disease or risk factors. Cardiovascular status should be assessed before initiating treatment and monitored throughout. Etoricoxib should be used for the shortest possible time and at the lowest effective dose.

Hypertension

Blood pressure should be monitored before initiating therapy and throughout treatment with etoricoxib. If blood pressure rises significantly, the benefit-risk ratio should be reconsidered and antihypertensive therapy optimised. Etoricoxib is contraindicated in patients with uncontrolled hypertension.

Gastrointestinal effects

GI bleeding, ulceration and perforation have been reported with NSAIDs. The lowest effective dose should be used. Patients with a history of GI disease (ulcers, bleeding) should use etoricoxib with caution; concomitant gastroprotective therapy (e.g. PPI or misoprostol) should be considered.

Renal and hepatic effects

Use with caution in patients at risk of acute kidney injury (dehydration, heart failure, renal insufficiency, on diuretics, ACE inhibitors or ARBs). Monitor renal function. Etoricoxib should be discontinued if progressive deterioration of renal function occurs. Hepatic effects: Monitor liver function tests during treatment. If transaminases rise to >3× ULN, discontinue etoricoxib.

Skin reactions

Serious skin reactions including SJS, TEN and exfoliative dermatitis, which can be fatal, have been reported with NSAIDs. Etoricoxib should be discontinued at the first signs of skin rash, mucosal lesions or any other sign of hypersensitivity.

Female fertility

As with other NSAIDs, the use of etoricoxib may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulty conceiving or who are undergoing investigation of infertility, withdrawal of etoricoxib should be considered.

Paraben content

This product contains methylparaben and propylparaben, which may cause allergic reactions (possibly delayed).

Erythrosine content

This product contains erythrosine supra (E127), a colouring agent. Erythrosine may cause allergic reactions, particularly in patients who are sensitive to aspirin or other tartrazine-related compounds.

Fever

The pharmacological nature of etoricoxib may mask fever and other signs and symptoms of inflammation, delaying the diagnosis of infectious complications.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulants and antiplatelet agents (warfarin, heparin, aspirin, clopidogrel):

Concomitant use may increase the risk of bleeding; close monitoring (INR, platelet function) is recommended.

ACE inhibitors and ARBs (enalapril, ramipril, losartan, valsartan):

NSAIDs may reduce the antihypertensive effect and, in patients with compromised renal function (e.g. dehydration, elderly), may increase the risk of acute renal failure. Monitor renal function and blood pressure.

Diuretics:

NSAIDs may attenuate the diuretic and antihypertensive effects.

Lithium:

NSAIDs may increase serum lithium levels; monitor for lithium toxicity.

Methotrexate:

NSAIDs may reduce methotrexate excretion and increase toxicity; exercise caution.

Ciclosporin:

Etoricoxib may increase the nephrotoxicity of ciclosporin.

Oral contraceptives (ethinyl estradiol):

Etoricoxib 120 mg increases the AUC of ethinylestradiol by 50–60%; this should be considered when selecting dose and formulation of oral contraceptives.

Alcohol:

Avoid alcohol during treatment, as the risk of GI bleeding may be increased.

4.6 Fertility, pregnancy and lactation

Pregnancy

Etoricoxib is contraindicated from 30 weeks of pregnancy onward. From 20 weeks, NSAIDs including etoricoxib may cause oligohydramnios resulting from foetal renal dysfunction; use should be limited to the lowest effective dose for the shortest duration, with antenatal monitoring if used in this period. There are no adequate human data for first-trimester use; use should be avoided unless clearly necessary.

Breast-feeding

Etoricoxib passes into breast milk; it is not recommended for nursing mothers.

Fertility

As with other NSAIDs, etoricoxib may impair female fertility. In women who have difficulty conceiving, withdrawal of etoricoxib should be considered.

4.7 Effects on ability to drive and use machines

Dizziness has been reported with etoricoxib. Patients who experience dizziness or somnolence should not drive or operate machinery.

4.8 Undesirable effects

Summary of the safety profile

The adverse reaction profile of ETOVAC-SP reflects primarily that of etoricoxib, a selective COX-2 inhibitor. The most commonly reported adverse reactions include hypertension, oedema, GI effects (dyspepsia, nausea, abdominal pain, diarrhoea), headache and dizziness. Serious but rare adverse reactions include GI bleeding/ulceration, cardiovascular thrombotic events, and severe skin reactions.

System Organ Class	Common	Uncommon / Rare
Infections	Upper respiratory infection	Urinary tract infection (uncommon)
Nervous system	Headache, dizziness	Somnolence (uncommon)
Vascular	Oedema, hypertension	Myocardial infarction, stroke (rare)
Gastrointestinal	Dyspepsia, nausea, abdominal pain, diarrhoea	GI ulcer, GI bleeding, constipation, flatulence, GERD (uncommon)
Hepatobiliary	Elevated liver enzymes	Hepatitis, jaundice (rare)
Skin		Rash, urticaria, pruritus, SJS, TEN, exfoliative dermatitis (rare)
Renal and urinary		Renal impairment, acute renal failure (uncommon/rare)

System Organ Class	Common	Uncommon / Rare
Musculoskeletal		Arthralgia, muscle cramps (uncommon)

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 via the National Regulatory Authority.

4.9 Overdose

Symptoms

Stomach pain, diarrhoea, flatulence, dyspepsia, peripheral oedema, headache, dizziness, nausea.

Treatment

Gastric lavage and general supportive measures. Etoricoxib is eliminated following biotransformation to inactive metabolites; haemodialysis is unlikely to be beneficial due to high protein binding.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug (NSAID), selective COX-2 inhibitor. ATC code: M01AH05 (etoricoxib); M09AB (serratiopeptidase).

Etoricoxib:

Selectively inhibits isoform 2 of the enzyme cyclooxygenase (COX-2), with approximately 106-fold selectivity for COX-2 over COX-1. This reduces the generation of prostaglandins from arachidonic acid, inhibiting inflammation and pain. Selective COX-2 inhibitors cause fewer gastrointestinal adverse effects than traditional non-selective NSAIDs due to relative preservation of COX-1 activity.

Serratiopeptidase:

A serine protease enzyme derived from the bacterium Serratia marcescens. Serratiopeptidase acts via the arachidonic acid pathway (COX-1 and COX-2), reducing inflammation and oedema by enzymatic breakdown of insoluble fibrin (a by-product of blood clot), causing thinning of inflammatory exudate and facilitating tissue drainage. This adjunctive anti-inflammatory and fibrinolytic activity complements the analgesic effect of etoricoxib.

5.2 Pharmacokinetic properties

Etoricoxib

Absorption: Orally administered etoricoxib is well absorbed; absolute bioavailability approximately 100%. Tmax approximately 1 hour after a 120 mg dose. AUC increases in proportion to dose over the range of 5–120 mg. Distribution: Extensively protein-bound, primarily to plasma albumin; apparent volume of distribution approximately 120 L. Biotransformation: Metabolised primarily by CYP3A4. Elimination: Excreted predominantly as inactive glucuronide and carboxylic acid metabolites in urine and faeces; <1% excreted unchanged in urine.

Serratiopeptidase

Absorption: Absorbed from the intestine following oral administration (as enteric-coated granules to protect from gastric acid degradation); absorption is dose-dependent as demonstrated in rat studies measuring plasma and lymph concentrations. Distribution: Distributed throughout body tissues via systemic circulation; reaches higher concentrations in inflamed tissues.

5.3 Preclinical safety data

Etoricoxib: Conventional preclinical safety studies with etoricoxib are well-established in the literature. No evidence of genotoxicity. NSAID class effects on renal and GI mucosa have been observed at high doses. Serratiopeptidase: No specific preclinical safety studies have been conducted for this combination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No.	Excipient	Specification
1	Dibasic calcium phosphate	BP
2	Maize starch	BP
3	Microcrystalline cellulose	BP
4	PVP K-30	BP
5	Methylparaben (excipient with known effect)	BP
6	Propylparaben (excipient with known effect)	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 methylcellulose (HPMC)	BP
13	Isopropyl alcohol	BP
14	Methylene dichloride	BP
15	Titanium dioxide (E171)	BP
16	Erythrosine supra (E127) (excipient with known effect)	IH
17	Monopropylene 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 and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container
10 tablets packed in one ALU-ALU blister; 3 such blisters packed in a carton with package insert. Pack size: 30 tablets.

6.6 Special precautions for disposal and other handling
No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
PROMED PHARMACEUTICALS LTD
P.O. Box 22953-00100, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
H2026/CTD12251/26528

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