SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

LETZGO GEL
(ETORICOXIB 1% W/W, LINSEED OIL 3% W/W, METHYL SALICYLATE 10% W/W AND MENTHOL 5% W/W GEL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Etoricoxib 1% w/w,
Linseed oil BP 3%w/w,
Methyl salicylate BP 10% w/w,
Menthol BP 5% w/w
(Preservative: Benzyl alcohol BP 1%w/w)

Batch Size: 5.00 kg

SN	Name of Ingredients	Spec	Qty per 30 gm (in g)	Qty per 100 gm (in g)	Ovg. %	Std. batch qty (in g)	Function
1	Etoricoxib	INH	0.300	1.00	--	52.00	Active
2.	Linseed oil	BP	0.900	3.00	--	150.00	Active
3.	Methyl salicylate	BP	3.00	10.00	--	500.00	Active
4.	Menthol	BP	1.50	5.00	--	250.00	Active
5.	Benzyl alcohol	BP	0.30	1.00	--	50.00	Preservative
6.	Propylene glycol	BP	1.20	4.00	--	200.00	Humectant
7.	Isopropyl alcohol	BP	0.60	2.00	--	100.00	Solvent
8.	Ethanol	BP	1.20	4.00	--	200.00	Solvent
9.	Diethylamine	BP	0.45	1.50	--	75.00	pH regulator
	Water Base						
10	Carbomer	BP	0.48	1.60	--	80.00	Emulsifier
11	Disodium Edetate	BP	0.03	0.10	--	5.00	Chelating agent
12	Purified Water	BP	q.s. to 30 gm	q.s. to 100 gm	--	q.s. to 5.0 Kgs.	Solvent
	Wax Phase						
13	Macrogols	BP	0.564	1.88	--	94.00	Oil phase
14	Cresmer RH 40	INH	1.05	3.50	--	175.00	Solubilizer
15	Butylated Hydroxy Toluene	BP	0.06	0.20	--	10.00	Antioxidant

INH: IN- House Specification

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

Topical gel

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

1. Osteoarthritis (OA),
2. Rheumatoid arthritis (RA),
3. Ankylosing spondylitis,
4. Pain and signs of inflammation associated with acute gouty arthritis.
5. For the short-term treatment of moderate pain associated with dental surgery.

4.2 Posology and Method of Administration

Route of administration**:** Topical

Posology:

To be used topically twice daily on the affected area or to be used it in the dose and duration advised by health practitioner.

Paediatric patients

Etoricoxib is contra-indicated in children and adolescents under 16 years of age.

4.3 Contraindications

i) Hypersensitivity to the active substance or to any of the excipients

ii) Active peptic ulceration or active gastro-intestinal (GI) bleeding

iii) Patients who have experienced bronchospasm, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria, or allergic-type reactions after taking acetylsalicylic acid or NSAIDs including COX-2 (cyclooxygenase-2) inhibitors

iv) Pregnancy and lactation

v) Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score ≥10)

vi) Estimated renal creatinine clearance <30 ml/min

vii) Children and adolescents under 16 years of age

viii) Inflammatory bowel disease

ix) Congestive heart failure

x) Patients with hypertension whose blood pressure is persistently elevated above 140/90mmHg and has not been adequately controlled.

xi) Established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease.

4.4 Special Warnings and Precautions for use

Paediatric use

This medicine is not recommended for use in patients below 16 years of age.

Gastrointestinal ulcers or bleeding

This medicine is not recommended for use in patients with a history of gastrointestinal ulcers or bleeding since it may worsen the patient's condition. Replacement with a suitable alternative should be considered under supervision.

Heart diseases

This medicine should be used with extreme caution in patients with a history of heart diseases since it may worsen the patient's condition.

Diarrhoea and dehydration

This medicine should be used with caution in patients suffering from diarrhoea or dehydration since it may worsen the patient's condition. Appropriate corrective measures, dose adjustments, or replacement with a suitable alternative may be necessary based on the clinical condition.

High blood pressure

This medicine should be used with caution in patients suffering from high blood pressure and receiving high blood pressure medicines due to the increased risk of altered blood pressure. Close monitoring of blood pressure levels is recommended for such patients. Appropriate dose adjustments or replacement with a suitable alternative may be necessary based on the clinical condition.

Infections

This medicine should be used with extreme caution in patients suffering from an infection since it may mask the symptoms of an infection such as a fever. More frequent clinical monitoring is recommended for such patients.

Oral Contraceptive

This medicine should be used with extreme caution in patients taking oral contraceptive medicines due to the increased risk of severe adverse effects. Report any unusual symptoms to the doctor immediately. Appropriate dose adjustments or replacement with a suitable alternative may be necessary based on the clinical condition.

4.5 Interaction with other medicinal products and other forms of interaction

Topical Etoricoxib may interact with Lithium, Ramipril, Warfarin, Ethinyl Estradiol and Primaquine.

4.6 Pregnancy and Lactation

Pregnancy

This medicine is not recommended for use in pregnant women unless absolutely necessary. All the risks and benefits should be discussed before taking this medicine or a safer alternative based on your clinical conditions may be considered.

Breast-feeding

This medicine is not recommended for use in breastfeeding women unless absolutely necessary. All the risks and benefits should be discussed before taking this medicine or a safer alternative based on your clinical conditions may be considered.

4.7 Effects on ability to drive and use machines

Patients who experience dizziness, vertigo or somnolence while using etoricoxib should refrain from driving or operating machinery.

4.8 Undesirable Effects

- Diarrhoea
- Nausea or vomiting
- Headache
- Dizziness
- Stomach pain
- Swelling of face, lips, eyelids, tongue, hands and feet

- Difficult and painful breathing
- Yellowing of skin and eyes
- Blurred vision
- Heart rhythm disorders
- Stevens-Johnson Syndrome
- Infections

4.9 Overdose

Symptoms of overdose may include skin rashes, confusion, chest pain, blurred vision etc.

5.1 Pharmacodynamic Properties

Therapeutic category: Anti Inflammatory, Anti rheumatic drug, Non – steroids,

Mechanism of action

It selectively inhibits the isoform 2 of the enzyme cyclooxygenase. It reduces the production of prostaglandins from arachidonic acids that helps relieves inflammation and pain. It is administered for arthritis, spondylitis and gout.

5.2 Pharmacokinetic Properties

Topical administration of etoricoxib is the most favoured route for management of ocular inflammation as it provides higher ocular drug concentrations, keeping away the systemic side effects associated with the oral administration.

5.3 Preclinical Safety Data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN.	Name of Ingredients	Specification	Function
1	Benzyl alcohol	BP	Preservative
2	Propylene glycol	BP	Humectant
3	Isopropyl alcohol	BP	Solvent
4	Ethanol	BP	Solvent
5	Diethylamine	BP	pH regulator
6	Carbomer	BP	Emulsifier/Stabilizer
7	Disodium Edetate	BP	Chelating agent
8	Purified Water	BP	Solvent
9	Macrogols	BP	Oil phase
10	Cresmer RH 40	INH	Solubilizer
11	Butylated Hydroxy Toluene	BP	Antioxidant

INH: IN- House Specification

BP: British Pharmacopoeia

6.2 Incompatibilities

None

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Store at temperatures not exceeding 30°C

6.5 Nature and contents of container

30 gm Tube

6.6 Special precautions for disposal and other handling

None such special requirement for disposing and handling the product.