

## SUMMARY OF PRODUCT CHARACTERISTICS

### **1. Name of the medicinal product:**

**TROFRINE** (Tropicamide & Phenylephrine Ophthalmic Solution)

### **2. Qualitative and Quantitative Composition:**

Tropicamide	USP	0.8% w/v
Phenylephrine Hydrochloride	USP	5% w/v
Chlorobutanol (As preservative)	BP	0.5% w/v
Aqueous Base		qs

### **3. Pharmaceutical form:**

Ophthalmic Solution.

### **4. Clinical particulars:**

#### **4.1 Therapeutic indications:**

Trofrine is indicated:

- to obtain pre-operative mydriasis,
- or for diagnostic purposes when monotherapy is known to be insufficient.

#### **4.2 Posology and method of administration:**

**Therapeutic purpose** 1-2 drops as required.

Diagnostic purpose/Pre-operative purpose: 1-2 drops in the eye(s) 15-30 minutes prior to the procedure.

#### **4.3 Contraindications:**

Trofrine should be used with caution in patients with glaucoma (increased pressure in the eye), heart diseases, hypertension (high blood pressure), blood clots, hormonal disorders, thyroid problems, diabetes, and tachycardia (increased heart rate).

#### **4.4 Special warnings and precautions for use:**

Use with caution when administered with, or up to 21 days after administration of MAO inhibitors as exaggerated adrenergic effects may result. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants.

#### **4.5 Interaction with other medicinal products and other forms of interaction:**

Trofrine may interact with a medicine used to treat low heart rate (atropine), antihypertensive agents, antidepressants (isocarboxazid, linezolid, selegiline, rasagiline, phenelzine, and tranlycypromine, etc.), anti-arrhythmic drug (quinidine), and general anaesthetic (halothane).

#### **4.6 Fertility, pregnancy and lactation:**

Trofrine is given by a doctor to pregnant women after doing a risk/benefit assessment. Please consult your doctor before using

#### **4.7 Effects on ability to drive and use machines:**

Trofrine may cause blurred vision. So, avoid driving or operating heavy machinery until your vision is clear.

#### **4.8 Undesirable effects:**

##### **Common Side Effect of Trofrine :**

- Eye pain
- Stinging in the eyes
- Blurred vision
- Photophobia
- Allergic reaction

#### **4.9 Overdose:**

Although unlikely due to single administration of Trofrine (for either pre-operative or diagnostic purposes), a risk of overdose may nevertheless occur in the event of the additional instillation of mydriatic eyedrops.

#### **5. Pharmacological properties:**

##### **5.1 Pharmacodynamic properties:**

Pharmacotherapeutic group: MYDRIATICS and CYCLOPLEGICS, Tropicamide combinations.

ATC code: S01F A56

Trofrine is an ophthalmic solution which combines two synthetic mydriatic agents (phenylephrine, alpha sympathomimetic, and tropicamide, anticholinergic).

Clinical trials have shown a time to reach a stable and sufficient mydriasis between 45 and 90 min. The maximal mydriasis (pupil diameter of 9 mm) was reached in 90 to 120 minutes.

The mydriasis, when reached, lasted at least 60 minutes.

##### **5.2 Pharmacokinetic properties:**

Tropicamide and Phenylephrine. Tropicamide is an anticholinergic, while Phenylephrine is a decongestant. They work by making the pupil of your eye larger and relaxing the muscles in your eye. This allows proper examination of the inside of your eye.

### **5.3 Preclinical safety data:**

Safety pharmacology, genotoxicity and conventional reproductive studies have not been conducted with phenylephrine, tropicamide or the fixed combination

## **6. Pharmaceutical particulars:**

### **6.1 List of excipients**

Sodium Nitrate  
Chlorobutanol  
Disodium EDTA  
Glycerin  
HPMC  
Polyvinyl Pyrrolidone K-30  
Tween-80  
Sodium Metabisulfite  
Purified water

### **6.2 Incompatibilities:**

None known.

### **6.3 Shelf life:**

24 months.

### **6.4 Special precautions for storage:**

Store in a cool dark place.  
Protect from light.

### **6.5 Nature and contents of container:**

5 ml sterile opaque plastic bottle with white cap packed in a carton along with pack insert.

### **6.6 Special precautions for disposal and other handling:**

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the tip to the eye or to any other surface.

There are no special precautions for disposal.

## **7. Marketing authorization holder:**

M/s. LinKabs Pharmaceuticals Ltd.,  
42 Ziks Avenue,  
Fegge- Onitsha Box 10239,  
Onitsha, Nigeria