

## **LUBTEAR EYE DROPS**

1.17.1 Product Information for Health Profession

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### **1. NAME OF THE MEDICINAL PRODUCT**

Lubtear Eye Drops

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains Dextran 70 USP 1.00 mg and Hypromellose USP 3.00 mg.

### **3. PHARMACEUTICAL FORM**

Eye drops, ophthalmic solution.

A clear colorless solution, free from any visible foreign particles filled & sealed in LDPE container fitted with natural/transparent LDPE nozzle and White HDPE cap.

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

As a lubricant and artificial tear in dry eye and other ocular irritation syndromes associated with deficient tear or mucous secretion. As a lubricant and artificial tear in dry eye and other ocular irritation syndromes associated with deficient tear or mucous secretion. This combination also prevents cornea to damage in patients with keratoconjunctivitis and for ocular lubrication. It is also used for the temporary relief of burning and irritation due to dryness of the eye and for use as the protectant against further irritation.

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

Adults, children and the elderly:

One or two drops three times daily or as directed by the physician.

#### **4.3 Contraindications**

This product contains Benzalkonium Chloride BP and should not be used when soft contact lenses are being worn.

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

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Lubtear contains Benzalkonium Chloride which may cause eye irritation and is known to discolour soft contact lenses. Contact with soft contact lenses is to be avoided. Patients should be advised to remove their contact lenses prior to the application of Lubtear and wait at least 15 minutes before reinsertion.

If patients experience headache, eye pain, vision changes, irritation of the eyes, persistent redness, or if the condition worsens or persists for more than 3 days, they are to discontinue use and consult their doctor.

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

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

#### **4.5 Pregnancy and lactation**

##### Pregnancy

There are no or limited amount of data from the use of Lubtear in pregnant women. However, the components dextran 70 and hypromellose exert a surface protective effect and are not pharmacologically active. These components are not expected to be absorbed systemically, to demonstrate any systemic toxicity or to have any effect on reproduction or embryofetal development. Lubtear can be used during pregnancy.

##### Lactation

It is unknown whether dextran 70, hypromellose or any of the components are excreted in human milk. Nonetheless, discontinuation of product use during breast-feeding is not considered necessary. Lubtear can be used during breast-feeding.

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

Lubtear has no or negligible influence on the ability to drive or use machines. As with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machines.

#### **4.7 Undesirable effects**

##### Summary of safety profile

The most frequently occurring adverse reaction during clinical trials was vision blurred.

##### Tabulated list of adverse reactions

The following adverse reactions are classified according to the following convention: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare

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( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ), or not known (cannot be estimated from the available data). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions were obtained from clinical trials and post marketing spontaneous reports.

System Organ Classification	MedDRA Preferred Term (v.12.0)
Immune system disorders	Not known: hypersensitivity
Nervous system disorders	Uncommon: headache
Eye disorders	Very common: vision blurred Common: dry eye (residual), eyelid disorder, abnormal sensation in eye, foreign body sensation in eyes, ocular discomfort. Uncommon: photophobia, hypoaesthesia eye, eye pruritus, eye irritation, ocular hyperaemia. Not known: erythema of eyelid, eye swelling, eye pain, eye discharge, eyelid margin crusting, lacrimation increased.
General disorders and administration site conditions	Uncommon: discomfort (skin)

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects can help on the safety of this medicine.

#### 4.9 Overdose

No case of overdose has been reported.

An overdose of Lubtear can easily be washed out of the eye with lukewarm tap water.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Lubricant and artificial tear

Dextran 70 ATC Code: B05AA05

Hypromellose (Methocel E4 M Premium) ATC code: S01XA20

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The combination of Dextran 70 and Hypromellose in an aqueous presentation provides a soothing lubricant preparation for the relief of dry eye syndrome associated with deficient tear secretion or deficient mucous.

## **5.2 Pharmacokinetic properties**

Not applicable.

## **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Benzalkonium chloride  
Disodium edetate  
Sodium chloride  
Potassium chloride  
Sodium hydroxide and/or Hydrochloric acid  
Water for Injection

### **6.2 Incompatibilities**

Not known.

### **6.3 Shelf life**

24 months (2 years)

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

Store below 30°C and do not freeze. Keep the container closed tightly after each opening.  
Keep out of reach of children.

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

Each plastic dropper bottle contains 10 ml of Dextran 70 USP & Hypromellose USP combination sterile solution.

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### **6.6 Special precautions for disposal <and other handling>**

No special requirements.

### **7 Market Authorization Holder**

Square Pharmaceuticals PLC.

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### **8 Marketing authorization number**

**H2019/CTD5125/1094ER**

### **9 Date of first authorization/renewal of the authorization**

**2019**

### **10 Date of revision of the text**

**31/03/2026**